

Redacted Data Submitted by the Primary Manufacturer and Other Interested Parties for Januvia

Below are redacted versions of the data submitted by the Primary Manufacturer and other interested parties in response to the Negotiation Program information collection request.¹ These redacted data have been redacted consistent with the confidentiality standards described in section 40.2 of the revised guidance and do not contain proprietary information, protected health information (PHI)/personally identifiable information (PII), or other information that is protected from disclosure under applicable law.

Respondents were permitted to include citations and attachments (hereinafter, collectively called “supplemental materials”) within their submissions for certain questions specified in the information collection request; therefore, you may observe that the number and order of any supplemental materials included as part of each response below will vary.

¹ The Negotiation Program information collection request is available on the Office of Management and Budget’s (OMB’s) website at the following link: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202306-0938-013 and described in section 50 of revised guidance.

Section 1194(e)(1) Data Factors

IPAY Year: 2026

Manufacturer: Merck Sharp Dohme

Drug: Januvia (Sitagliptin)

Background: For the first year of the Medicare Drug Price Negotiation Program (“the Negotiation Program”), CMS selected 10 Part D high expenditure, single source drugs for negotiation. Section 1194(e) of the Act requires Centers for Medicare & Medicaid Services (CMS) to consider two sets of factors as the basis for determining the offer and counteroffer throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug. After entering into an agreement under the Negotiation Program with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug submitted to CMS the following information with respect to a selected drug: information that CMS required to carry out negotiation, including but not limited to the factors listed in section 1194(e)(1) of the Act. For IPAY 2026, the Primary Manufacturer of each selected drug were tasked to provide the following data factors for each of its selected drug(s), which were specifically:

- C: Research and Development Costs and Recoupment,
- D: Current Unit Costs of Production and Distribution,
- E: Prior Federal Financial Support,
- F: Patents, Exclusivities, and Approvals, and
- G: Market Data and Revenue and Sales Volume Data.

The Primary Manufacturer is responsible for aggregating and reporting all necessary data on its selected drug(s) from other parties, as applicable.

Disclaimers: With the exclusion of publicly available data, all manufacturer submitted data is considered proprietary and confidential. The data contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document.

Note: Primary Manufacturers submitted required data in the Health Plan Management System (HPMS). Please note that the format of manufacturer responses is dependent on the data element requested. For example, some requested responses are “yes or no”, while other response options in HPMS provided a drop-down menu. However, some responses could be more complex and subjective, such as dollar

amounts, cost per unit, etc. For many questions, the ICR instructs the manufacturer to include an explanation. In some instances, an explanation is required and in other instances, the ICR directs the user to include an explanation “as necessary.” CMS instructs manufacturers to indicate “n/a” if they choose not to include an explanation in this case.

C. Research and Development Cost							
<p>Description: Section C contains five questions, related to different types of R&D costs incurred by the Primary Manufacturer, including acquisition costs. Each of these questions required the Primary Manufacturer to report, as applicable: (1) dollar amounts for R&D costs, which must be reported in the numerical response field and (2) explanations of how those costs were calculated in the free response field. Section C also contains one question about the Primary Manufacturer’s global and U.S. total lifetime net revenue for the selected drug. This question required the Primary Manufacturer to report, as applicable: (1) the dollar amount for global, total lifetime net revenue, which must be reported in the numerical response field, (2) an explanation of how this amount was calculated in the free response field, (3) the dollar amount for U.S. lifetime net revenue, which must be reported in the numerical response field, and (4) an explanation of how this amount was calculated in the free response field.</p>							
Primary Manufacturer Acquisition Costs of the Selected Drug	Total Acquisition Costs for the Selected Drug	Basic Pre-Clinical Research for All Approved Indications of the Selected Drug	Post-IND Costs for All Approved Indications of the Selected Drug	Costs of Failed or Abandoned Products Related to the Selected Drug	Direct Costs of Other R&D for the Selected Drug Not Accounted for Above	Global Total Lifetime Net Revenue for the Selected Drug	U.S. Total Lifetime Net Revenue for the Selected Drug

Explanations:

Explanation of Allocation of Total Acquisition Costs for the Selected Drug

None.

Explanation of Basic Pre-Clinical Research Costs

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

Introductory Comments

Merck has endeavored in good faith to address these R&D requests, but these questions presented fail to fully reflect how R&D is undertaken for drug discovery and development. For important explanatory information regarding the Research & Development (R&D) innovation process and discovery of JANUVIA® and list of cited references for Section C, please see Merck's overview contained within the free text field for Question 5. Merck respectfully requests that this information be read in advance of the responses provided for Questions 2, 3, and 4. Due to system limitations, Merck is unable to include this background information within Question 1 or 2 in the order it is intended to be read.

Pre-clinical research necessarily involves extensive experimentation and learning across multiple targets and modalities. Discovery and early development research by their nature are foundational and cross-cutting, thwarting efforts to retrospectively calculate investments to a specific successful candidate. Pre-clinical R&D includes more than new targets and candidates; to progress to a drug, investment in medicinal chemistry is critical. Narratives of the discovery and development of new medicines often focus disproportionately on the scientific research and testing to validate the disease target and the biological pathway to reach it. Equally important is the medicinal chemistry and manufacturing science required to achieve the practical "druggability" of a molecule (or molecules) to realize its full potential in the treatment of disease. Investment across a range of candidates and targets is necessarily broader for discovery and early development, as innovators work through the complex process of hypothesis generation and testing of candidates. This persistent complexity and uncertainty has meant that the chances of getting an early stage candidate (entering Phase 1 trial) through licensure remain less than one in 10 (1).

The discovery and early development of sitagliptin (later trademarked as JANUVIA®) marked a first-in-class novel treatment for Type 2 Diabetes that offered new and valued benefits for patients and healthcare systems in the US and globally. Scientific evidence for a hormone called GLP-1 (glucagon-like peptide-1) in signaling the pancreas to release insulin and the importance of an enzyme called DPP-4 (dipeptidyl peptidase-4) in regulating the levels of GLP-1 in the body led to excitement regarding the potential for DPP-4 inhibition to treat patients with Type 2 Diabetes by preventing the breakdown of endogenous incretin that work with high blood sugar to stimulate the secretion of insulin after a meal.

In August 1999, when Merck scientists initiated the program to discover a novel inhibitor of DPP-4, injectable GLP-1 treatments were already well validated, and Merck's initiative to validate a DPP-4 inhibitor was undertaken to identify an alternate, oral approach to GLP-1 therapy (2). Both GLP-1 and DPP-4 inhibitor candidates were developed as an improvement over the then standard of care in terms of disease control and patient benefit (2). As explained in Merck's response to Question 5, in early 2000, to accelerate the program, Merck invested in several candidates from a German biotechnology company (2). Unfortunately, preclinical safety studies showed that the molecules were toxic. Subsequently the team systematically tested more than 800,000 additional molecules searching for candidates with greater specificity. Two promising candidates that inhibited DPP-4 were identified but they lacked the potency and were therefore unsuitable (3).

Using the latest techniques, Merck medicinal chemists worked diligently to refine and engineer new molecules with enhanced potency. More than 2,000 additional new molecules were synthesized, prepared, and investigated. Eventually the team narrowed the search to six possible candidates, of which a single candidate subsequently named sitagliptin (MK-0431) was chosen to advance (3). Only a fraction of the investment costs undertaken in that broader task to validate the DPP-4 target and find an inhibitor can be specifically accounted to sitagliptin or the small set of failed and abandoned products reportable herein; but without a doubt, all that investment was necessary to achieve the innovation.

The request in Question 2 is to provide details on basic pre-clinical research costs for JANUVIA®, limiting the accounting of costs to those incurred from the date of initial discovery to the day before the IND application. This unduly narrow construct ignores much of the substantial efforts, expenditures, and accomplishments vital to the discovery of JANUVIA®, but which necessarily preceded its discovery. In addition, because Question 2 limits costs attributable solely to the ultimately successful candidate molecule (sitagliptin), it ignores the reality that early R&D activities are, by their nature, foundational, cross-cutting, and not confined from an accounting standpoint to a single, specific successful candidate.

Reported Costs: Explanation and Methodology

Background: Merck reports aggregate R&D costs through its quarterly and annual financial results, which are available in the public domain as part of its periodic Securities Exchange Commission (SEC) 10-Q and 10-K filings.

[REDACTED]

[REDACTED]

Merck's research division – which primarily oversees R&D functions within the company – is called Merck Research Laboratories.

[REDACTED]

CMS Guidance, however, defines the starting point of the “basic pre-clinical research period” based on the “date of initial discovery” in cases where such date can be determined for the selected drug. [REDACTED]

[REDACTED]

R&D Costs Not Captured Because of Limitations Contemplated by CMS Guidance: CMS Guidance excludes costs incurred on discovery and development of the selected drug prior to the “initial date of discovery.” As explained above, considerable time, effort, and expenditures of R&D resources are required to reach the point of “discovery.” [REDACTED]

[REDACTED] Any measure of R&D that fails to account for these pre-clinical costs inherently undervalues the substantial expenditures associated with discovering and developing new medicines. This is particularly true with groundbreaking, first-in-class medicines like JANUVIA®, which required exploration of novel targets and pathways.

Explanation of Post-IND Costs

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

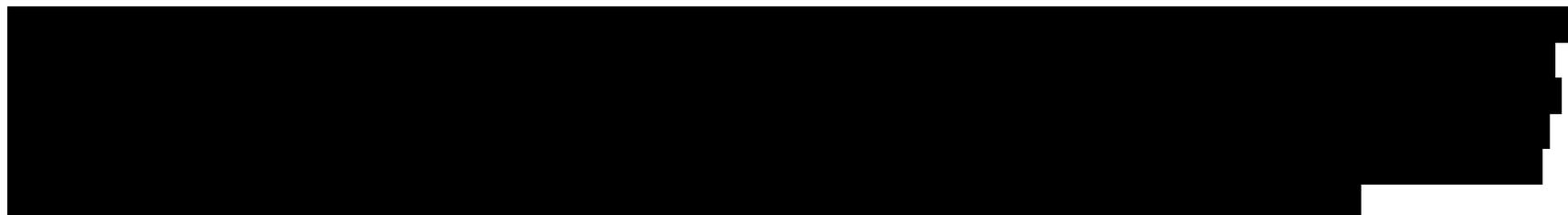
Introductory Comments

The “D” in R&D is often described in terms of investment in clinical trials, and this certainly was an important part of the JANUVIA® investment story. In addition to the cost of clinical trials, considerable investment was also committed and remains committed on an ongoing basis for regulatory, safety and manufacturing to bring JANUVIA® through development and sustain it through its lifetime. The company made major investments in preclinical and clinical trials which further showed the promise of sitagliptin and allowed Merck clinical scientists to identify a therapeutic dose. Based on the magnitude of the unmet need for patients with Type 2 Diabetes, and the potential promise of the molecule, Merck decided to take the financial risk and conduct the Phase II trials in a larger patient population and over a longer duration simultaneously.

Investing in a biomarker strategy of plasma DPP-4 inhibition provided an effective translation from the preclinical studies in other species to the clinic, which allowed for accurate dose selection from Phase I data. This innovative approach not only helped to drive the clinical program but also to reduce the time to the start of Phase III study by 1.4 years (in contemporary comparison to other development projects)(3). This delivered both an efficiency in development and also a benefit to patients involved in the clinical trials.

Positive safety and efficacy findings from the Phase II studies of MK-0431 in patients with diabetes supported proceeding to even larger studies. Phase III studies, which involved thousands of patients in the U.S., Canada, South America, Europe, Asia, South Africa, Australia, and New Zealand, were conducted to obtain sufficient evidence for regulatory approval.

Clinical research also included efficacy of JANUVIA® as an add-on therapy to metformin or pioglitazone in patients that were inadequately controlled with either of these two established medicines (3). Studies like these provided important additional options and helped to establish the value of the medicine in the context of standard of care regimens.



Although the guidance limits the calculation of costs to the end of the last FDA-required post-marketing trial, this does not account for the end of R&D investment in medicines like JANUVIA®. Safety monitoring and evaluation, and in some cases additional safety studies, continue throughout the lifetime of the medicine as new science and new questions emerge. Likewise, manufacturing is a continuous innovation process,

as Merck finds new opportunities and new challenges. Regulatory requirements on all products continue and evolve long after the initial establishment of a medicine. Merck's recent R&D investments to develop measures to address the potential formation of nitrosamines in response to emerging regulatory interest highlight as one example the extent to which R&D innovation continues after approval and extends into areas beyond discovery and clinical research. All these investments are critical parts of the development process of a successful medicine and should be considered alongside the clinical trial costs.

Lastly, CMS Guidance for reporting R&D costs for the selected drug states that manufacturers should report those costs for only approved indications. The lives of many patients are improved, and saved, by virtue of continued R&D that follows a medication's initial approval. Discovery of new indications is only possible because of the substantial risks manufacturers take in pursuing those that fail.

Reported Costs: Explanation and Methodology

Background: Merck reports aggregate R&D costs through its quarterly and annual financial results, which are available in the public domain as part of its periodic SEC 10-Q and 10-K filings.

[REDACTED]

[REDACTED] Merck's research division – which primarily oversees R&D functions within the company – is called Merck Research Laboratories.

[REDACTED]

Additional Information: The FDA reviewed JANUVIA®'s initial NDA pursuant to a standard review and provided approval ten months after filing.

R&D Costs Not Captured Because of Limitations Contemplated by CMS Guidance: As noted above, CMS Guidance excludes reporting of R&D costs for the selected drug that do not relate to the labeled indication. Thus, calculations according to CMS Guidance preclude a full accounting of true R&D costs relating to the selected drug and excludes investments made by manufacturers to advance treatments for additional diseases.

Explanation of Costs on Allowable Failed or Abandoned Products Related to the Selected Drug

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

Introductory Comments

[REDACTED] but research takes a broader scope which often results in failed or abandoned products that still lead to significant new scientific knowledge. Merck recognizes the aims in CMS Guidance to account not only for the selected drug (JANUVIA®) but for a 'portion of the direct costs' spent on basic pre-clinical research and clinical research for failed or abandoned candidates related to JANUVIA®. CMS Guidance contains a similar reference, contemplating that manufacturers include "[f]ailed or abandoned product costs" that are the "sum of the portion of direct basic pre-clinical research costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct post-IND costs for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval." [REDACTED]

[REDACTED]

However, Merck emphasizes that the response to Question 4 fails to adequately capture the invested R&D that was necessary for the development and licensure of JANUVIA[®], but which failed to yield any direct income itself. Merck's R&D investment, from which JANUVIA[®] was developed, follows the evolving biological and disease science to explore different targets and mechanisms of action, with no guarantee of any successful candidate but yielding new scientific knowledge and practice. Moreover, basic research and discovery work is foundational investment that supports an array of candidates (failed/abandoned or successful). [REDACTED]

[REDACTED]

[REDACTED]

As such, retrospective accounting focusing only on a successful medicine fails to consider the full R&D investment undertaken and that must continue to be pursued across therapeutic areas where science and technology offers new opportunities, funded by the subset of candidate medicines that succeed.

[REDACTED]

Reported Costs: Explanation and Methodology

Background: Merck reports aggregate R&D costs through its quarterly and annual financial results, which are available in the public domain as part of its periodic SEC10-Q and 10-K filings. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Merck's research division – which primarily oversees R&D functions within the company – is called Merck Research Laboratories. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Costs Methodology: [REDACTED]

Timeframes: For each failed/abandoned candidate, Merck reported R&D expenditures incurred during the pre-clinical and post-IND time periods for JANUVIA[®], detailed above in Questions 2 and 3, respectively.

Failed/Abandoned R&D Costs Not Captured: Because CMS Guidance states that reportable costs should be limited to (a) drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and (b) drugs in the same therapeutic class as JANUVIA[®] [REDACTED]

Explanation of Costs of Other R&D

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

Overview and Explanatory Background Comments regarding Discovery of JANUVIA[®] and R&D Process (see cross-reference in narrative for Question 2)

Merck's considerable investments, undertaking substantial risk, in a broad portfolio across multiple therapeutic areas over several decades serve as the foundation of transformative scientific innovations like JANUVIA[®]. Merck has a proud legacy of translating cutting-edge science into medicines and vaccines that save and improve lives. The company invests significant resources to invent therapeutic candidates with the potential to provide unambiguous advantages to patients and payers. These candidates undergo rigorous and extensive evaluation in large and costly clinical trial programs to demonstrate safety and effectiveness. A significant number of these trials ultimately do not yield a regulatory approved product. [REDACTED]

Innovation in medicines depends on effective and productive R&D, in the context of profound scientific uncertainty and rapid technological change. Although public awareness often focuses on the innovation of a single successfully licensed product, research-based biopharmaceutical innovators like Merck invest in a broad research portfolio over many years and across many disciplines. This research reality sharply contrasts with the artificially narrow and unrepresentative reporting framework regarding R&D required by CMS Guidance. A more complete measure of R&D would need to recognize that every success draws from many lines of pursuit of R&D not only in that therapeutic domain but across scientific fields, disciplines, and technologies. CMS' approach not only underestimates the full investment required for JANUVIA[®], but more importantly it misses the nature and cadence of biopharmaceutical R&D, where exploration of science is iterative and requires understanding not only the breakthroughs but also the failures. Many researchers at Merck and our peers have made critical scientific contributions to discovery despite never touching a candidate that ultimately was approved for the treatment of patients.

Most of Merck's portfolio investment, undertaken at substantial risk and with a notable rate of program attrition, does not directly result in a licensed medicine or vaccine. Instead, the investment advances Merck's scientific understanding across biology, pharmaceutical, regulatory and data science, and provides the inputs for the next R&D projects, within and across therapeutic areas. This portfolio investment indirectly contributes to every successfully licensed product, including JANUVIA®. Without that broader portfolio research, many successful products like JANUVIA® would never be developed. In addition, a first-in-class innovator faces costs beyond scientific R&D, as they must work through hurdles educating stakeholders and establishing a new therapeutic offering in health systems globally (and from which following next-in-class drug developers benefit). These efforts and associated expenditures are often overlooked when measuring R&D costs by focusing principally on pre-clinical research and clinical trial costs.

Diabetes is a global epidemic with profound socio-economic burden. Merck's commitment toward diabetes has been steadfast. According to the World Health Organization, the worldwide incidence of Types 1 and 2 diabetes rose from 108 million in 1980 to 422 million in 2014(5). Other estimates calculate that 8.8% of the world's population suffered from diabetes in 2017 (6). Diabetes is a progressive condition and without effective treatments and careful management can lead to blindness, kidney failure, heart attacks, stroke, and the need for lower limb amputation(7). The socioeconomic effects of diabetes are particularly severe, as prevalence amongst middle-aged (between 40 – 59) people is greatest (6). Given this profound and growing burden on patients and society, Merck has invested at considerable risk and succeeded in establishing a proud legacy of treatments.

Merck has made a long-standing commitment to address diabetes, which is exemplified by its first-in-class and award-winning medicine, JANUVIA®. This medicine, which resulted from internal R&D and not acquisition, was the inspirational innovation of two women scientists, Nancy Thornberry and Ann Weber, who won the PhRMA 2011 Discoverers Award for this breakthrough to recognize special achievements of exceptional benefit to humankind (8). This was a first for Merck – the first two women in the company's history to lead a team that discovered a new medicine – and for the Discoverers Award to have a women-only celebrated team.

Merck's R&D achievements in this space extend to the often-overlooked innovation required to design, scale, and optimize manufacture of new medicines to meet patient needs in environmentally sustainable ways. With the predicted tremendous global demand for an effective diabetes treatment, Merck understood the need for a reliable and robust manufacturing process. Merck undertook additional effort to identify and develop a more efficient, environmentally friendly, "green" synthesis of sitagliptin (9). Merck received two Environmental Protection Agency's Presidential Green Chemistry Challenge Awards for these novel manufacturing techniques, one with Solvias for rhodium catalyzed and the other with Codexis for the enzymatic process. These methodologies now provide the basis for the synthesis of multiple pharmaceutical manufacturing processes. This further exemplifies the criticality and application of JANUVIA®'s innovation beyond diabetes and the limitation of accounting approaches, such as the one contemplated by CMS' guidance, in ascribing R&D costs to specific candidates.

The medicinal chemistry in discovering and developing JANUVIA® has been a critical part of the overall discovery and development of this medicine. This achievement was recognized by the American Chemical Society (ACS) in its award of the 'Heroes of Chemistry' award in 2010 to

Nancy Thornberry, Ann Weber and Joseph D Armstrong III (10). While Thornberry and Weber led the overall Discovery Science Team, Joe Armstrong led the Process Research Development Team that designed, developed, and implemented the manufacturing process for the active pharmaceutical ingredient (API) in JANUVIA®.

Acquisition of external research projects can be an important input to R&D for new treatments. In fact, two candidates were in-licensed to help kick off Merck's DPP-4 research program, which was prompted by scientific evidence for a hormone called GLP-1 (glucagon-like peptide-1) in signaling the pancreas to release insulin (2). Merck scientists postulated that the DPP-4 enzyme's role in regulating GLP-1 in the body could mean that DPP-4 inhibition would help treat patients with type 2 diabetes mellitus (T2D). Both in-licensed candidates failed; they had unacceptable toxicity because they were not sufficiently specific to DPP-4, and they inhibited related molecules in the body. Learning from these failed candidates, the Merck team then focused on internal R&D to continue to explore the DPP-4 pathway and candidates with greater specificity, systematically testing more than 800,000 molecules (8) in the process. After nearly three years of investment, the Merck team selected in 2001 one of these internally developed pre-clinical stage molecules to progress and that later became JANUVIA®.

Explanation for Value Reported in Question 5 and "Other" R&D Costs: Merck does not have any costs associated with conducting FDA-required post-marketing trials that were not completed.

Merck notes, however, that it continues to incur ongoing R&D costs relating to JANUVIA® that do not appear reportable based upon the limitations contemplated by CMS Guidance. [REDACTED]

[REDACTED] Moreover, as explained in our responses to Questions 8 and 13, Merck has made substantial investments in R&D to develop additional API processing steps to address the potential formation of nitrosamines, which emerged as a matter of regulatory interest long after JANUVIA®'s launch.

References

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7. American Chemical Society. New 'Heroes of Chemistry' invented medicines that help millions of people: [phys.org](https://phys.org/news/2010-08-heroes-chemistry-medicines-millions-people.html); 2010 [updated 7 August 2023]. Available from: <https://phys.org/news/2010-08-heroes-chemistry-medicines-millions-people.html>.
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9. Dowden H, Munro J. Trends in clinical success rates and therapeutic focus. *Nat Rev Drug Discov*. 2019;18(7):495-6.
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Explanation of Global Lifetime Net Revenue

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

Explanation:



Explanation of U.S. Lifetime Net Revenue

Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

Explanation:



D. Current Unit Costs of Production and Distribution

Background: Manufacturers were required to report production and distribution unit costs separately for each NDC-11 of the selected drug, including any NDC-11 of the selected drug marketed by a Secondary Manufacturer. A free response field was provided to explain the methodology for calculating the amount reported.

NDC-11	Average Per Unit Production Cost	Average Per Unit Distribution Costs	Indicate Unit Used	Total Unit Volume
00006-0112-28			EA	
00006-0112-31			EA	
00006-0112-54			EA	
00006-0221-28			EA	
00006-0221-31			EA	
00006-0221-54			EA	
00006-0277-28			EA	
00006-0277-31			EA	
00006-0277-54			EA	
00006-0277-82			EA	

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Against this backdrop, Merck has described below the methodology and relevant assumptions in providing the per unit production and distribution costs for JANUVIA® NDCs set forth in response to ICR Request No. 7:

[REDACTED]

Other notes and assumptions:

[Redacted]



E. Federal Financial Support

Description: This section pertains to all prior federal financial support provided by federal agencies or federally supported grants or contracts that contributed to direct costs for the basic pre-clinical research and clinical trials phase of research and development for FDA-approved indications of the selected drug to the Primary Manufacturer only. It also pertains to prior federal financial support received for indirect costs of developing the selected drug.

Total Federal Financial Support	Federal Financial Support	Type of Agreement	Federal Agency(ies) Participating in Agreement	Nature of Agreement
	(refer to Explanations)	OTH		

Explanations:

Federal Financial Support

"Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

F. Patents, Exclusivities, and Approvals

Patents (Expired and Non-Expired) and Patent Applications

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This table lists each patent that is related to the selected drug, as well as each application for a patent related to the selected drug that is pending with the USPTO.

Patent #	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book / Purple Book
US 6,303,661	1998-10-07	2017-04-24	N	N	Y	N	UTL	Y
US 6,699,871	2002-07-05	2022-07-26	Y	Y	Y	N	UTL	Y
US 6,890,898	2002-07-03	2019-02-02	N	N	Y	N	UTL	Y
US 7,078,381	2004-03-04	2019-02-02	N	N	Y	N	UTL	Y
US 7,125,873	2003-12-19	2022-07-26	N	N	Y	N	UTL	Y
US 7,326,708	2004-06-23	2026-11-24	Y	Y	Y	N	UTL	Y
US 7,459,428	2006-07-17	2019-02-02	N	N	Y	N	UTL	Y
US 8,318,669	2010-11-09	2019-02-02	N	N	Y	N	UTL	N
US 8,513,190	2011-11-16	2019-02-02	N	N	Y	N	UTL	N
US 9,044,424	2013-07-25	2019-02-02	N	N	Y	N	UTL	N
US 7,468,459	2004-03-15	2025-03-30	N	N	N	N	UTL	N
US 7,495,123	2005-04-05	2025-03-30	N	N	N	N	UTL	N
US 7,612,072	2005-09-09	2026-04-11	N	N	N	N	UTL	N
US 9,833,463	2015-04-13	2035-04-13	N	N	N	N	UTL	N
USSN 63/418282; Proprietary	2022-10-21	9999-12-31	Y	Y	N	Y	UTL	N
US 8,293,507	2010-02-26	2030-09-01	N	N	N	N	UTL	N
US 8,889,380	2012-09-05	2030-07-11	N	N	N	N	UTL	N

F. Patents, Exclusivities, and Approvals

Patents (Expired and Non-Expired) and Patent Applications

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This table lists each patent that is related to the selected drug, as well as each application for a patent related to the selected drug that is pending with the USPTO.

Patent #	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book / Purple Book
US 9,587,229	2012-06-18	2032-06-18	N	N	N	N	UTL	N
US 9,523,107	2015-08-14	2034-02-24	N	N	N	N	UTL	N

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b) (3-4)), 18 USC § 1905, and CMS Guidance § 40.2.1.

JANUVIA® is a small molecule product used to treat type 2 diabetes. The chemical compound sitagliptin is the active ingredient in JANUVIA®. Sitagliptin inhibits a protein known as dipeptidyl peptidase IV (“DPP-4”), a regulatory enzyme involved in modulating the level of insulin (and thus glucose) in the human body. Approved in 2006, JANUVIA® was the first DPP-4 inhibitor (“DPP-4i”) approved by the FDA for the treatment of diabetes. After synthesizing sitagliptin and identifying its biological activity, Merck worked to develop a stable solid form of the compound that could be formulated into a finished drug product. This research led to the synthesis and identification of the dihydrogen phosphate (“DHP”) salt of sitagliptin as the lead solid form candidate and, eventually, to the crystalline monohydrate form of the DHP salt, which is the solid form of sitagliptin used in JANUVIA®.

In the list of patents/patent applications provided in Question 12, three cover the sitagliptin active ingredient (US’871, USSN 63/418282 and US’708). Patent US’871 (expired) claims the compound sitagliptin and pharmaceutically acceptable salts thereof. Pending provisional patent application USSN 63/418282 was filed reflecting research conducted at the request of FDA to reduce the potential for forming nitrosamine impurities within JANUVIA®. Patent US’708 claims the DHP salt of sitagliptin and hydrates thereof. The exclusivity of this patent ends on May 24, 2027, upon expiration of 6 months of pediatric exclusivity extension added to the patent term. The patentability of US’708 was also challenged and affirmed by the US Patent Office (a decision that was further affirmed by the Federal Appeals Court) and the US District Court. Nevertheless, Merck agreed that certain companies can bring their generic versions of JANUVIA® to the market in May 2026, or earlier under certain circumstances.

[REDACTED]

Seven of the patents, US'661, US'898, US'381, US'428, US'669, US'190, and US'424 (all expired), were non-exclusively licensed and generally covered methods of treating diabetes, regulating glucagon-like peptide 1 metabolism, or modifying glucose metabolism using a DPP-4i. None of these patents specifically disclosed or claimed sitagliptin or a method of using sitagliptin.

One patent, US'873 (expired), covered methods of treating type 2 diabetes with sitagliptin and metformin or insulin, two uses described in JANUVIA®'s label.

Six of the patents, US'459, US'229, US'107, US'123, US'507 and US'380, resulted from investment in processes to manufacture sitagliptin, including a rhodium catalyzed process (US'123) and an enzyme catalyzed process (US'507 and US'380) that were awarded two Presidential Green Chemistry Challenge awards from the US Environmental Protection Agency.

Additional information is provided below:

US 6,699,871 claims the compound sitagliptin and pharmaceutically acceptable salts thereof.

US 7,326,708 claims the DHP salt of sitagliptin, which is the specific drug substance of JANUVIA®. This patent expires November 24, 2026, which includes 884 days patent term adjustment as provided under 35 USC 154, and has a 6 month pediatric exclusivity extension that expires May 24, 2027. Merck has agreed that certain companies can bring their generic versions of "JANUVIA®" to the market in May 2026, or earlier under certain circumstances. [REDACTED]

USSN 63/418282: This pending unpublished patent application is proprietary.

[REDACTED]

[REDACTED]

US 6,303,661 was non-exclusively licensed by Merck and is directed to a method for lowering elevated blood glucose levels with a DPP-4i. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin.

US 6,890,898 was non-exclusively licensed by Merck and is directed to a method for modifying glucose metabolism with a DPP-4i and insulin, or with a DPP-4i and metformin. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin.

US 7,078,381 was non-exclusively licensed by Merck and is directed to a method of treating type 2 diabetes with a DPP-4i and insulin. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin.

US 7,459,428 was non-exclusively licensed by Merck and is directed to a method for treating type 2 diabetes with a DPP-4i and metformin. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin. The Certificate of Correction for US 7,459,428 states "This invention was made with government support under Grant AI040228 awarded by the National Institutes of Health. The government has certain rights in the invention."

US 8,318,669 was non-exclusively licensed by Merck and is directed to a method for modification and regulation of GLP-1 metabolism with a DPP-4i. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin.

US 8,513,190 was non-exclusively licensed to Merck and is directed to a method for modification and regulation of type 2 diabetes with a DPP-4i. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin.

US 9,044,424 was non-exclusively licensed by Merck and is directed to a method for modification and regulation of glucose metabolism with a DPP-4i. It does not disclose or claim sitagliptin and does not specifically claim the use of sitagliptin.

US 8,293,507 and US 8,889,380 were non-exclusively licensed by Merck and are each directed to a process to manufacture sitagliptin.

F. Patents, Exclusivities, and Approvals

Regulatory Exclusivity Periods

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Manufacturers reported all regulatory exclusivity periods under the FD&C Act or the PHS Act that are listed in the Orange Book or the Purple Book and in effect or have expired for the selected drug.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA/BLA) Number	NDC-9s Covered by Exclusivity	Comments
CEE	2011-10-16	21995	[REDACTED]	NCE The following statements are applicable to all exclusivities listed in this submission: (1) [REDACTED] [REDACTED] (2) Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic versions of "JANUVIA®" to the market in May 2026 or earlier, under certain circumstances.
CIE	2010-10-16	21995	[REDACTED]	New Clinical Investigation Exclusivity with FDA Code M-68: "description of results of study of initial therapy in combination with metformin when diet and exercise do not provide glycemic control." Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic versions of JANUVIA® to the market in May 2026 or earlier, under certain circumstances.
CIE	2010-10-16	21995	[REDACTED]	New Clinical Investigation Exclusivity with FDA Code M-69: "results of study of combination therapy and non-inferiority study."

F. Patents, Exclusivities, and Approvals

Regulatory Exclusivity Periods

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Manufacturers reported all regulatory exclusivity periods under the FD&C Act or the PHS Act that are listed in the Orange Book or the Purple Book and in effect or have expired for the selected drug.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA/BLA) Number	NDC-9s Covered by Exclusivity	Comments
				Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic versions of JANUVIA® to the market in May 2026 or earlier, under certain circumstances.
CIE	2022-08-12	21995	[REDACTED]	New Clinical Investigation Exclusivity with FDA Code M-244: "information added to the labeling regarding efficacy and safety of the continuation of sitagliptin compared with the withdrawal of sitagliptin during initiation and titration of insulin glargine in subjects with Type 2 diabetes mellitus." Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic versions of JANUVIA® to the market in May 2026 or earlier, under certain circumstances.
PED	2023-02-12	21995	[REDACTED]	PED extension of New Clinical Investigation Exclusivity with FDA Code M-244. Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic

F. Patents, Exclusivities, and Approvals

Regulatory Exclusivity Periods

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Manufacturers reported all regulatory exclusivity periods under the FD&C Act or the PHS Act that are listed in the Orange Book or the Purple Book and in effect or have expired for the selected drug.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA/BLA) Number	NDC-9s Covered by Exclusivity	Comments
				versions of JANUVIA® to the market in May 2026 or earlier, under certain circumstances.
CIE	2023-12-04	21995	[REDACTED]	New Clinical Investigation Exclusivity with FDA Code M-187: "addition of clinical information obtained from a pediatric trial to section 8.4 of the labeling." Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic versions of JANUVIA® to the market in May 2026 or earlier, under certain circumstances.
PED	2024-06-04	21995	[REDACTED]	PED extension of New Clinical Investigation Exclusivity M-187. Notwithstanding unexpired regulatory exclusivities to which it may be entitled, Merck has consented to certain generic approvals in connection with license agreements with certain companies, enabling those companies to bring their generic versions of "JANUVIA®" to the market in May 2026 or earlier, under certain circumstances.
PED	2023-01-26	21995	[REDACTED]	Pediatric exclusivity extension applicable with respect to Orange Book-listed patents. In 2020, the 6-month pediatric exclusivity extension was granted for JANUVIA® and applied to all Orange Book-listed patents, including US Patent 6,699,871, for which the

F. Patents, Exclusivities, and Approvals

Regulatory Exclusivity Periods

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Manufacturers reported all regulatory exclusivity periods under the FD&C Act or the PHS Act that are listed in the Orange Book or the Purple Book and in effect or have expired for the selected drug.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA/BLA) Number	NDC-9s Covered by Exclusivity	Comments
				patent term expired July 26, 2022 (and related 6 months pediatric exclusivity expired on January 26, 2023).
PED	2023-01-26	21995	[REDACTED]	Pediatric exclusivity extension applicable with respect to Orange Book-listed patents. In 2020, the 6-month pediatric exclusivity extension was granted for JANUVIA® and applied to all Orange Book-listed patents, including US Patent 7,125,873, for which the patent term expired July 26, 2022 (and related 6 months pediatric exclusivity expired on January 26, 2023).
PED	2027-05-24	21995	[REDACTED]	Pediatric exclusivity extension applicable with respect to Orange Book-listed patents. In 2020, the 6-month pediatric exclusivity extension was granted for JANUVIA® and applied to all Orange Book-listed patents, including US Patent 7,326,708, for which the patent term expires November 24, 2026 (and related 6 months pediatric exclusivity expires on May 24, 2027).

Explanations: None.

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
21995	NDA	1	2006-10-16	<p>Monotherapy: JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Combination Therapy: JANUVIA® is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin or a PPARγ agonist (e.g., thiazolidinediones) when the single agent alone, with diet and exercise, does not</p>	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	Initial approval

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
				provide adequate glycemic control.				
21995	NDA	1	2007-10-12	Monotherapy and Combination Therapy JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. [See Clinical Studies (14).]	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)
21995	NDA	1	2007-10-12	Monotherapy and Combination Therapy JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
				mellitus. [See Clinical Studies (14).]				
21995	NDA	1	2010-02-26	JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. [See Clinical Studies (14).]	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)
21995	NDA	1	2010-02-26	JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. [See Clinical Studies (14).]	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)
21995	NDA	1	2010-02-26	JANUVIA® is indicated as an adjunct to diet and exercise to	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of	APP	(refer to Explanations)

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
				improve glycemic control in adults with type 2 diabetes mellitus. [See Clinical Studies (14).]		Merck & Co., Inc.		
21995	NDA	1	2010-09-24	JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. [See Clinical Studies (14).]	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)
21995	NDA	1	2019-08-12	JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
21995	NDA	1	2020-12-04	JANUVIA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	Tablets, 25mg, 50mg & 100mg	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	APP	(refer to Explanations)

Explanations: Per CMS's instructions for Question 15, information about efficacy supplements (as classified by FDA on Drugs@FDA per 21 C.F.R. 314.3) has been included but other supplements have not been included. Supplements do not have Classification Codes listed on the Drugs@FDA website, so the Classification Code from the original NDA 021995 being supplemented is listed.

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0112-28	2018-Q3	\$14.32	EA	
00006-0112-31	2018-Q3	\$14.32	EA	
00006-0112-54	2018-Q3	\$14.32	EA	
00006-0221-28	2018-Q3	\$14.32	EA	
00006-0221-31	2018-Q3	\$14.32	EA	
00006-0221-54	2018-Q3	\$14.32	EA	
00006-0277-28	2018-Q3	\$14.32	EA	
00006-0277-31	2018-Q3	\$14.32	EA	
00006-0277-54	2018-Q3	\$14.32	EA	
00006-0277-82	2018-Q3	\$14.32	EA	
00006-0112-28	2018-Q4	\$14.32	EA	
00006-0112-31	2018-Q4	\$14.32	EA	
00006-0112-54	2018-Q4	\$14.32	EA	
00006-0221-28	2018-Q4	\$14.32	EA	
00006-0221-31	2018-Q4	\$14.32	EA	
00006-0221-54	2018-Q4	\$14.32	EA	
00006-0277-28	2018-Q4	\$14.32	EA	
00006-0277-31	2018-Q4	\$14.32	EA	
00006-0277-54	2018-Q4	\$14.32	EA	
00006-0277-82	2018-Q4	\$14.32	EA	
00006-0112-28	2019-Q1	\$15.04	EA	
00006-0112-31	2019-Q1	\$15.04	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0112-54	2019-Q1	\$15.04	EA	
00006-0221-28	2019-Q1	\$15.04	EA	
00006-0221-31	2019-Q1	\$15.04	EA	
00006-0221-54	2019-Q1	\$15.04	EA	
00006-0277-28	2019-Q1	\$15.04	EA	
00006-0277-31	2019-Q1	\$15.04	EA	
00006-0277-54	2019-Q1	\$15.04	EA	
00006-0277-82	2019-Q1	\$15.04	EA	
00006-0112-28	2019-Q2	\$15.04	EA	
00006-0112-31	2019-Q2	\$15.04	EA	
00006-0112-54	2019-Q2	\$15.04	EA	
00006-0221-28	2019-Q2	\$15.04	EA	
00006-0221-31	2019-Q2	\$15.04	EA	
00006-0221-54	2019-Q2	\$15.04	EA	
00006-0277-28	2019-Q2	\$15.04	EA	
00006-0277-31	2019-Q2	\$15.04	EA	
00006-0277-54	2019-Q2	\$15.04	EA	
00006-0277-82	2019-Q2	\$15.04	EA	
00006-0112-28	2019-Q3	\$15.04	EA	
00006-0112-31	2019-Q3	\$15.04	EA	
00006-0112-54	2019-Q3	\$15.04	EA	
00006-0221-28	2019-Q3	\$15.04	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0221-31	2019-Q3	\$15.04	EA	
00006-0221-54	2019-Q3	\$15.04	EA	
00006-0277-28	2019-Q3	\$15.04	EA	
00006-0277-31	2019-Q3	\$15.04	EA	
00006-0277-54	2019-Q3	\$15.04	EA	
00006-0277-82	2019-Q3	\$15.04	EA	
00006-0112-28	2019-Q4	\$15.04	EA	
00006-0112-31	2019-Q4	\$15.04	EA	
00006-0112-54	2019-Q4	\$15.04	EA	
00006-0221-28	2019-Q4	\$15.04	EA	
00006-0221-31	2019-Q4	\$15.04	EA	
00006-0221-54	2019-Q4	\$15.04	EA	
00006-0277-28	2019-Q4	\$15.04	EA	
00006-0277-31	2019-Q4	\$15.04	EA	
00006-0277-54	2019-Q4	\$15.04	EA	
00006-0277-82	2019-Q4	\$15.04	EA	
00006-0112-28	2020-Q1	\$15.78	EA	
00006-0112-31	2020-Q1	\$15.78	EA	
00006-0112-54	2020-Q1	\$15.78	EA	
00006-0221-28	2020-Q1	\$15.78	EA	
00006-0221-31	2020-Q1	\$15.78	EA	
00006-0221-54	2020-Q1	\$15.78	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0277-28	2020-Q1	\$15.78	EA	
00006-0277-31	2020-Q1	\$15.78	EA	
00006-0277-54	2020-Q1	\$15.78	EA	
00006-0277-82	2020-Q1	\$15.78	EA	
00006-0112-28	2020-Q2	\$15.78	EA	
00006-0112-31	2020-Q2	\$15.78	EA	
00006-0112-54	2020-Q2	\$15.78	EA	
00006-0221-28	2020-Q2	\$15.78	EA	
00006-0221-31	2020-Q2	\$15.78	EA	
00006-0221-54	2020-Q2	\$15.78	EA	
00006-0277-28	2020-Q2	\$15.78	EA	
00006-0277-31	2020-Q2	\$15.78	EA	
00006-0277-54	2020-Q2	\$15.78	EA	
00006-0277-82	2020-Q2	\$15.78	EA	
00006-0112-28	2020-Q3	\$15.78	EA	
00006-0112-31	2020-Q3	\$15.78	EA	
00006-0112-54	2020-Q3	\$15.78	EA	
00006-0221-28	2020-Q3	\$15.78	EA	
00006-0221-31	2020-Q3	\$15.78	EA	
00006-0221-54	2020-Q3	\$15.78	EA	
00006-0277-28	2020-Q3	\$15.78	EA	
00006-0277-31	2020-Q3	\$15.78	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0277-54	2020-Q3	\$15.78	EA	
00006-0277-82	2020-Q3	\$15.78	EA	
00006-0112-28	2020-Q4	\$15.78	EA	
00006-0112-31	2020-Q4	\$15.78	EA	
00006-0112-54	2020-Q4	\$15.78	EA	
00006-0221-28	2020-Q4	\$15.78	EA	
00006-0221-31	2020-Q4	\$15.78	EA	
00006-0221-54	2020-Q4	\$15.78	EA	
00006-0277-28	2020-Q4	\$15.78	EA	
00006-0277-31	2020-Q4	\$15.78	EA	
00006-0277-54	2020-Q4	\$15.78	EA	
00006-0277-82	2020-Q4	\$15.78	EA	
00006-0112-28	2021-Q1	\$16.56	EA	
00006-0112-31	2021-Q1	\$16.56	EA	
00006-0112-54	2021-Q1	\$16.56	EA	
00006-0221-28	2021-Q1	\$16.56	EA	
00006-0221-31	2021-Q1	\$16.56	EA	
00006-0221-54	2021-Q1	\$16.56	EA	
00006-0277-28	2021-Q1	\$16.56	EA	
00006-0277-31	2021-Q1	\$16.56	EA	
00006-0277-54	2021-Q1	\$16.56	EA	
00006-0277-82	2021-Q1	\$16.56	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0112-28	2021-Q2	\$16.56	EA	
00006-0112-31	2021-Q2	\$16.56	EA	
00006-0112-54	2021-Q2	\$16.56	EA	
00006-0221-28	2021-Q2	\$16.56	EA	
00006-0221-31	2021-Q2	\$16.56	EA	
00006-0221-54	2021-Q2	\$16.56	EA	
00006-0277-28	2021-Q2	\$16.56	EA	
00006-0277-31	2021-Q2	\$16.56	EA	
00006-0277-54	2021-Q2	\$16.56	EA	
00006-0277-82	2021-Q2	\$16.56	EA	
00006-0112-28	2021-Q3	\$16.56	EA	
00006-0112-31	2021-Q3	\$16.56	EA	
00006-0112-54	2021-Q3	\$16.56	EA	
00006-0221-28	2021-Q3	\$16.56	EA	
00006-0221-31	2021-Q3	\$16.56	EA	
00006-0221-54	2021-Q3	\$16.56	EA	
00006-0277-28	2021-Q3	\$16.56	EA	
00006-0277-31	2021-Q3	\$16.56	EA	
00006-0277-54	2021-Q3	\$16.56	EA	
00006-0277-82	2021-Q3	\$16.56	EA	
00006-0112-28	2021-Q4	\$16.56	EA	
00006-0112-31	2021-Q4	\$16.56	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0112-54	2021-Q4	\$16.56	EA	
00006-0221-28	2021-Q4	\$16.56	EA	
00006-0221-31	2021-Q4	\$16.56	EA	
00006-0221-54	2021-Q4	\$16.56	EA	
00006-0277-28	2021-Q4	\$16.56	EA	
00006-0277-31	2021-Q4	\$16.56	EA	
00006-0277-54	2021-Q4	\$16.56	EA	
00006-0277-82	2021-Q4	\$16.56	EA	
00006-0112-28	2022-Q1	\$17.38	EA	
00006-0112-31	2022-Q1	\$17.38	EA	
00006-0112-54	2022-Q1	\$17.38	EA	
00006-0221-28	2022-Q1	\$17.38	EA	
00006-0221-31	2022-Q1	\$17.38	EA	
00006-0221-54	2022-Q1	\$17.38	EA	
00006-0277-28	2022-Q1	\$17.38	EA	
00006-0277-31	2022-Q1	\$17.38	EA	
00006-0277-54	2022-Q1	\$17.38	EA	
00006-0277-82	2022-Q1	\$17.38	EA	
00006-0112-28	2022-Q2	\$17.38	EA	
00006-0112-31	2022-Q2	\$17.38	EA	
00006-0112-54	2022-Q2	\$17.38	EA	
00006-0221-28	2022-Q2	\$17.38	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0221-31	2022-Q2	\$17.38	EA	
00006-0221-54	2022-Q2	\$17.38	EA	
00006-0277-28	2022-Q2	\$17.38	EA	
00006-0277-31	2022-Q2	\$17.38	EA	
00006-0277-54	2022-Q2	\$17.38	EA	
00006-0277-82	2022-Q2	\$17.38	EA	
00006-0112-28	2022-Q3	\$17.38	EA	
00006-0112-31	2022-Q3	\$17.38	EA	
00006-0112-54	2022-Q3	\$17.38	EA	
00006-0221-28	2022-Q3	\$17.38	EA	
00006-0221-31	2022-Q3	\$17.38	EA	
00006-0221-54	2022-Q3	\$17.38	EA	
00006-0277-28	2022-Q3	\$17.38	EA	
00006-0277-31	2022-Q3	\$17.38	EA	
00006-0277-54	2022-Q3	\$17.38	EA	
00006-0277-82	2022-Q3	\$17.38	EA	
00006-0112-28	2022-Q4	\$17.38	EA	
00006-0112-31	2022-Q4	\$17.38	EA	
00006-0112-54	2022-Q4	\$17.38	EA	
00006-0221-28	2022-Q4	\$17.38	EA	
00006-0221-31	2022-Q4	\$17.38	EA	
00006-0221-54	2022-Q4	\$17.38	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0277-28	2022-Q4	\$17.38	EA	
00006-0277-31	2022-Q4	\$17.38	EA	
00006-0277-54	2022-Q4	\$17.38	EA	
00006-0277-82	2022-Q4	\$17.38	EA	
00006-0112-28	2023-Q1	\$18.24	EA	
00006-0112-31	2023-Q1	\$18.24	EA	
00006-0112-54	2023-Q1	\$18.24	EA	
00006-0221-28	2023-Q1	\$18.24	EA	
00006-0221-31	2023-Q1	\$18.24	EA	
00006-0221-54	2023-Q1	\$18.24	EA	
00006-0277-28	2023-Q1	\$18.24	EA	
00006-0277-31	2023-Q1	\$18.24	EA	
00006-0277-54	2023-Q1	\$18.24	EA	
00006-0277-82	2023-Q1	\$18.24	EA	
00006-0112-28	2023-Q2	\$18.24	EA	
00006-0112-31	2023-Q2	\$18.24	EA	
00006-0112-54	2023-Q2	\$18.24	EA	
00006-0221-28	2023-Q2	\$18.24	EA	
00006-0221-31	2023-Q2	\$18.24	EA	
00006-0221-54	2023-Q2	\$18.24	EA	
00006-0277-31	2023-Q2	\$18.24	EA	
00006-0277-54	2023-Q2	\$18.24	EA	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
00006-0277-82	2023-Q2	\$18.24	EA	
00006-0277-28	2023-Q2		EA	

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b)(3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.

The WAC prices reported in Question 16 reflect the price in effect on the last day of each quarter noted.

In reporting units for Question 16, Merck has omitted discontinued NDCs 00006027702, 00006027727, 00006027730, and 00006027733, because these NDCs were not sold or distributed to any wholesaler or direct purchaser during the most recent five years.

[REDACTED]

[REDACTED]

Merck has compared the WAC prices listed in Question 16 to the data for those NDC-11s reported by Medi-Span, FDB (First Databank), and RED BOOK®. Merck has not identified any discrepancies between the WAC prices listed in Question 16 and what was published in these pricing compendia. Merck has not analyzed the data from any other pricing service and Merck may not be aware of all pricing services that exist.

G. Market Data and Revenue and Sales Volume Data

Medicaid Best Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.

Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	00006-0112	2018-Q3		EA	
Y	00006-0221	2018-Q3		EA	
Y	00006-0277	2018-Q3		EA	
Y	00006-0112	2018-Q4		EA	
Y	00006-0221	2018-Q4		EA	
Y	00006-0277	2018-Q4		EA	
Y	00006-0112	2019-Q1		EA	
Y	00006-0221	2019-Q1		EA	
Y	00006-0277	2019-Q1		EA	
Y	00006-0112	2019-Q2		EA	
Y	00006-0221	2019-Q2		EA	
Y	00006-0277	2019-Q2		EA	
Y	00006-0112	2019-Q3		EA	
Y	00006-0221	2019-Q3		EA	
Y	00006-0277	2019-Q3		EA	
Y	00006-0112	2019-Q4		EA	
Y	00006-0221	2019-Q4		EA	
Y	00006-0277	2019-Q4		EA	
Y	00006-0112	2020-Q1		EA	
Y	00006-0221	2020-Q1		EA	

G. Market Data and Revenue and Sales Volume Data

Medicaid Best Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.

Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	00006-0277	2020-Q1		EA	
Y	00006-0112	2020-Q2		EA	
Y	00006-0221	2020-Q2		EA	
Y	00006-0277	2020-Q2		EA	
Y	00006-0112	2020-Q3		EA	
Y	00006-0221	2020-Q3		EA	
Y	00006-0277	2020-Q3		EA	
Y	00006-0112	2020-Q4		EA	
Y	00006-0221	2020-Q4		EA	
Y	00006-0277	2020-Q4		EA	
Y	00006-0112	2021-Q1		EA	
Y	00006-0221	2021-Q1		EA	
Y	00006-0277	2021-Q1		EA	
Y	00006-0112	2021-Q2		EA	
Y	00006-0221	2021-Q2		EA	
Y	00006-0277	2021-Q2		EA	
Y	00006-0112	2021-Q3		EA	
Y	00006-0221	2021-Q3		EA	
Y	00006-0277	2021-Q3		EA	
Y	00006-0112	2021-Q4		EA	

G. Market Data and Revenue and Sales Volume Data

Medicaid Best Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.

Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	00006-0221	2021-Q4		EA	
Y	00006-0277	2021-Q4		EA	
Y	00006-0112	2022-Q1		EA	
Y	00006-0221	2022-Q1		EA	
Y	00006-0277	2022-Q1		EA	
Y	00006-0112	2022-Q2		EA	
Y	00006-0221	2022-Q2		EA	
Y	00006-0277	2022-Q2		EA	
Y	00006-0112	2022-Q3		EA	
Y	00006-0221	2022-Q3		EA	
Y	00006-0277	2022-Q3		EA	
Y	00006-0112	2022-Q4		EA	
Y	00006-0221	2022-Q4		EA	
Y	00006-0277	2022-Q4		EA	
Y	00006-0112	2023-Q1		EA	
Y	00006-0221	2023-Q1		EA	
Y	00006-0277	2023-Q1		EA	
Y	00006-0112	2023-Q2		EA	
Y	00006-0221	2023-Q2		EA	
Y	00006-0277	2023-Q2		EA	

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b)(3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.

As permitted by CMS guidance, Merck routinely restates both Best Price and AMP within 36 months after these monthly and quarterly prices are originally due. [REDACTED]

As permitted by CMS guidance, in calculating the AMP eligible packages reported in Question 18 for each quarter, [REDACTED] [REDACTED] These AMP-ineligible units reflect Merck contracted sales made from a wholesaler to an AMP-ineligible end customer, such as a Federal purchaser or 340B Covered Entity.

[REDACTED]

Medicaid Best Price values are reported to CMS in dollar amounts rounded to six decimal places. However, for Question 18, the HPMS system prevents manufacturers from entering Best Price in values other than whole dollars and cents (i.e., a dollar amount with two decimal places). Therefore, Merck has rounded the Best Price values reported in Question 18 to two decimal places.

In accordance with CMS guidance on the submission of data elements in HPMS, updated on 9/28/2023, due to the limitations on the selection of unit types for Question 18, Merck selected “Each (EA)”; however, the correct unit type, which Merck uses to report AMP and Best Price for these NDCs, is TAB (Tablet).

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0112-28	2018-01-01 - 2018-08-31	\$1,095.04	EA	
Y	00006-0112-31	2018-01-01 - 2018-08-31	\$276.26	EA	
Y	00006-0112-54	2018-01-01 - 2018-08-31	\$828.75	EA	
Y	00006-0221-28	2018-01-01 - 2018-08-31	\$1,095.04	EA	
Y	00006-0221-31	2018-01-01 - 2018-08-31	\$328.52	EA	
Y	00006-0221-54	2018-01-01 - 2018-08-31	\$985.55	EA	
Y	00006-0277-02	2018-01-01 - 2018-08-31	\$365.46	EA	
Y	00006-0277-28	2018-01-01 - 2018-08-31	\$1,095.04	EA	
Y	00006-0277-31	2018-01-01 - 2018-08-31	\$276.26	EA	
Y	00006-0277-54	2018-01-01 - 2018-08-31	\$828.75	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-82	2018-01-01 - 2018-08-31	\$9,208.72	EA	
Y	00006-0112-28	2018-09-01 - 2018-12-31	\$1,367.24	EA	
Y	00006-0112-31	2018-09-01 - 2018-12-31	\$410.17	EA	
Y	00006-0112-54	2018-09-01 - 2018-12-31	\$1,230.51	EA	
Y	00006-0221-28	2018-09-01 - 2018-12-31	\$1,367.24	EA	
Y	00006-0221-31	2018-09-01 - 2018-12-31	\$410.17	EA	
Y	00006-0221-54	2018-09-01 - 2018-12-31	\$1,230.51	EA	
Y	00006-0277-02	2018-09-01 - 2018-12-31	\$422.34	EA	
Y	00006-0277-28	2018-09-01 - 2018-12-31	\$1,367.24	EA	
Y	00006-0277-31	2018-09-01 - 2018-12-31	\$410.17	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-54	2018-09-01 - 2018-12-31	\$1,230.51	EA	
Y	00006-0277-82	2018-09-01 - 2018-12-31	\$13,672.36	EA	
Y	00006-0112-28	2019-01-01 - 2019-12-31	\$1,367.19	EA	
Y	00006-0112-31	2019-01-01 - 2019-12-31	\$410.12	EA	
Y	00006-0112-54	2019-01-01 - 2019-12-31	\$1,230.46	EA	
Y	00006-0221-28	2019-01-01 - 2019-12-31	\$1,367.19	EA	
Y	00006-0221-31	2019-01-01 - 2019-12-31	\$410.12	EA	
Y	00006-0221-54	2019-01-01 - 2019-12-31	\$1,230.46	EA	
Y	00006-0277-28	2019-01-01 - 2019-12-31	\$1,367.19	EA	
Y	00006-0277-31	2019-01-01 - 2019-12-31	\$410.12	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-54	2019-01-01 - 2019-12-31	\$1,230.46	EA	
Y	00006-0277-82	2019-01-01 - 2019-12-31	\$13,672.31	EA	
Y	00006-0112-28	2020-01-01 - 2020-12-31	\$1,390.56	EA	
Y	00006-0112-31	2020-01-01 - 2020-12-31	\$417.14	EA	
Y	00006-0112-54	2020-01-01 - 2020-12-31	\$1,251.51	EA	
Y	00006-0221-28	2020-01-01 - 2020-12-31	\$1,390.56	EA	
Y	00006-0221-31	2020-01-01 - 2020-12-31	\$417.14	EA	
Y	00006-0221-54	2020-01-01 - 2020-12-31	\$1,251.51	EA	
Y	00006-0277-28	2020-01-01 - 2020-12-31	\$1,390.56	EA	
Y	00006-0277-31	2020-01-01 - 2020-12-31	\$417.14	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-54	2020-01-01 - 2020-12-31	\$1,251.51	EA	
Y	00006-0277-82	2020-01-01 - 2020-12-31	\$13,906.11	EA	
Y	00006-0112-28	2021-01-01 - 2021-12-31	\$1,409.62	EA	
Y	00006-0112-31	2021-01-01 - 2021-12-31	\$422.85	EA	
Y	00006-0112-54	2021-01-01 - 2021-12-31	\$1,268.65	EA	
Y	00006-0221-28	2021-01-01 - 2021-12-31	\$1,409.62	EA	
Y	00006-0221-31	2021-01-01 - 2021-12-31	\$422.85	EA	
Y	00006-0221-54	2021-01-01 - 2021-12-31	\$1,268.65	EA	
Y	00006-0277-28	2021-01-01 - 2021-12-31	\$1,409.62	EA	
Y	00006-0277-31	2021-01-01 - 2021-12-31	\$422.85	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-54	2021-01-01 - 2021-12-31	\$1,268.65	EA	
Y	00006-0277-82	2021-01-01 - 2021-12-31	\$14,096.62	EA	
Y	00006-0112-28	2022-01-01 - 2022-12-31	\$1,479.30	EA	
Y	00006-0112-31	2022-01-01 - 2022-12-31	\$443.76	EA	
Y	00006-0112-54	2022-01-01 - 2022-12-31	\$1,331.37	EA	
Y	00006-0221-28	2022-01-01 - 2022-12-31	\$1,479.30	EA	
Y	00006-0221-31	2022-01-01 - 2022-12-31	\$443.76	EA	
Y	00006-0221-54	2022-01-01 - 2022-12-31	\$1,331.37	EA	
Y	00006-0277-28	2022-01-01 - 2022-12-31	\$1,479.30	EA	
Y	00006-0277-31	2022-01-01 - 2022-12-31	\$443.76	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-54	2022-01-01 - 2022-12-31	\$1,331.37	EA	
Y	00006-0277-82	2022-01-01 - 2022-12-31	\$14,793.42	EA	
Y	00006-0112-28	2023-01-01 - 2023-12-31	\$1,552.54	EA	
Y	00006-0112-31	2023-01-01 - 2023-12-31	\$465.73	EA	
Y	00006-0112-54	2023-01-01 - 2023-12-31	\$1,397.30	EA	
Y	00006-0221-28	2023-01-01 - 2023-12-31	\$1,552.54	EA	
Y	00006-0221-31	2023-01-01 - 2023-12-31	\$465.73	EA	
Y	00006-0221-54	2023-01-01 - 2023-12-31	\$1,397.30	EA	
Y	00006-0277-28	2023-01-01 - 2023-12-31	\$1,552.54	EA	
Y	00006-0277-31	2023-01-01 - 2023-12-31	\$465.73	EA	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code (NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-54	2023-01-01 - 2023-12-31	\$1,397.30	EA	[REDACTED]
Y	00006-0277-82	2023-01-01 - 2023-12-31	\$15,525.94	EA	[REDACTED]

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b)(3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.

[REDACTED]

The prices reported in Question 20 represent package prices for the NDC-11 indicated, whereas the Total Unit Volume represents Unit Type EA (tablets).

The total unit volumes reported in Question 20 are reported using the invoice date of each transaction. These values were current as of the date they were retrieved, which was in July 2023.

For calendar year 2023, Merck's reported Federal Supply Schedule Prices are effective through 12/31/2023; however, the units reported reflect 1Q2023 and 2Q2023 Federal purchases only.

[REDACTED]

G. Market Data and Revenue and Sales Volume Data

Big Four Price

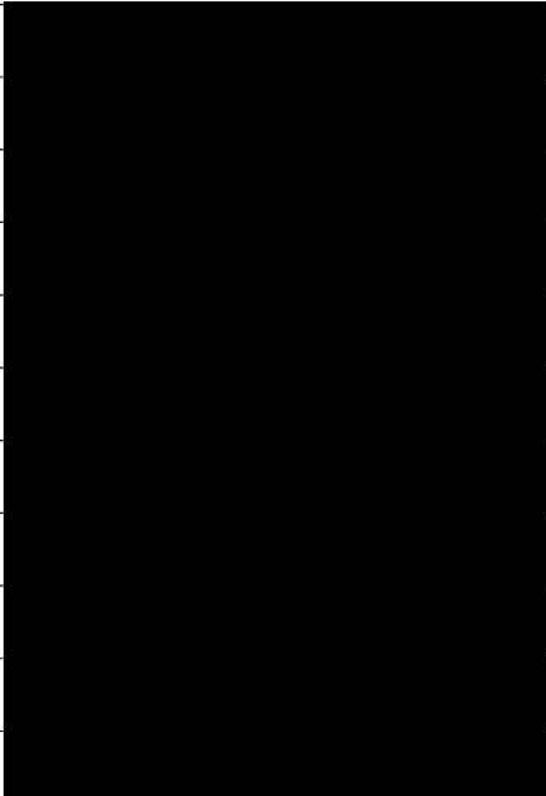
Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code (NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0112-28	2018-01-01 - 2018-12-31	\$825.02	EA	
Y	00006-0112-31	2018-01-01 - 2018-12-31	\$256.12	EA	
Y	00006-0112-54	2018-01-01 - 2018-12-31	\$751.53	EA	
Y	00006-0221-28	2018-01-01 - 2018-12-31	\$823.20	EA	
Y	00006-0221-31	2018-01-01 - 2018-12-31	\$255.41	EA	
Y	00006-0221-54	2018-01-01 - 2018-12-31	\$753.69	EA	
Y	00006-0277-02	2018-01-01 - 2018-12-31	\$265.29	EA	
Y	00006-0277-28	2018-01-01 - 2018-12-31	\$828.63	EA	
Y	00006-0277-31	2018-01-01 - 2018-12-31	\$256.32	EA	
Y	00006-0277-54	2018-01-01 - 2018-12-31	\$764.06	EA	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code (NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0277-82	2018-01-01 - 2018-12-31	\$8,423.96	EA	
Y	00006-0112-28	2019-01-01 - 2019-12-31	\$927.94	EA	
Y	00006-0112-31	2019-01-01 - 2019-12-31	\$289.51	EA	
Y	00006-0112-54	2019-01-01 - 2019-12-31	\$871.88	EA	
Y	00006-0221-28	2019-01-01 - 2019-12-31	\$929.91	EA	
Y	00006-0221-31	2019-01-01 - 2019-12-31	\$289.86	EA	
Y	00006-0221-54	2019-01-01 - 2019-12-31	\$871.06	EA	
Y	00006-0277-28	2019-01-01 - 2019-12-31	\$940.65	EA	
Y	00006-0277-31	2019-01-01 - 2019-12-31	\$289.81	EA	
Y	00006-0277-54	2019-01-01 - 2019-12-31	\$869.97	EA	
Y	00006-0277-82	2019-01-01 - 2019-12-31	\$9,740.35	EA	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code (NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0112-28	2020-01-01 - 2020-12-31	\$1,003.71	EA	
Y	00006-0112-31	2020-01-01 - 2020-12-31	\$314.59	EA	
Y	00006-0112-54	2020-01-01 - 2020-12-31	\$943.81	EA	
Y	00006-0221-28	2020-01-01 - 2020-12-31	\$1,004.75	EA	
Y	00006-0221-31	2020-01-01 - 2020-12-31	\$314.87	EA	
Y	00006-0221-54	2020-01-01 - 2020-12-31	\$942.44	EA	
Y	00006-0277-28	2020-01-01 - 2020-12-31	\$1,018.10	EA	
Y	00006-0277-31	2020-01-01 - 2020-12-31	\$314.81	EA	
Y	00006-0277-54	2020-01-01 - 2020-12-31	\$943.48	EA	
Y	00006-0277-82	2020-01-01 - 2020-12-31	\$10,490.07	EA	
Y	00006-0112-28	2021-01-01 - 2021-12-31	\$1,038.87	EA	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code (NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0112-31	2021-01-01 - 2021-12-31	\$328.60	EA	
Y	00006-0112-54	2021-01-01 - 2021-12-31	\$982.93	EA	
Y	00006-0221-28	2021-01-01 - 2021-12-31	\$1,028.59	EA	
Y	00006-0221-31	2021-01-01 - 2021-12-31	\$328.60	EA	
Y	00006-0221-54	2021-01-01 - 2021-12-31	\$980.98	EA	
Y	00006-0277-28	2021-01-01 - 2021-12-31	\$1,056.21	EA	
Y	00006-0277-31	2021-01-01 - 2021-12-31	\$329.16	EA	
Y	00006-0277-54	2021-01-01 - 2021-12-31	\$985.36	EA	
Y	00006-0277-82	2021-01-01 - 2021-12-31	\$10,942.55	EA	
Y	00006-0112-28	2022-01-01 - 2022-12-31	\$1,127.38	EA	
Y	00006-0112-31	2022-01-01 - 2022-12-31	\$361.45	EA	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

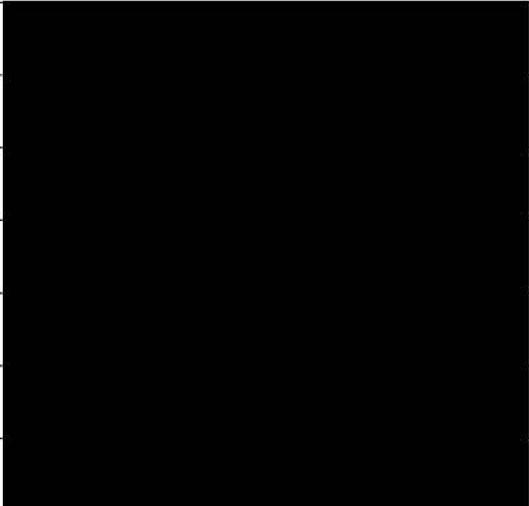
Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code (NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0112-54	2022-01-01 - 2022-12-31	\$1,075.92	EA	
Y	00006-0221-28	2022-01-01 - 2022-12-31	\$1,169.37	EA	
Y	00006-0221-31	2022-01-01 - 2022-12-31	\$360.94	EA	
Y	00006-0221-54	2022-01-01 - 2022-12-31	\$1,076.01	EA	
Y	00006-0277-28	2022-01-01 - 2022-12-31	\$1,139.08	EA	
Y	00006-0277-31	2022-01-01 - 2022-12-31	\$361.79	EA	
Y	00006-0277-54	2022-01-01 - 2022-12-31	\$1,072.35	EA	
Y	00006-0277-82	2022-01-01 - 2022-12-31	\$12,095.85	EA	
Y	00006-0112-28	2023-01-01 - 2023-12-31	\$1,187.60	EA	
Y	00006-0112-31	2023-01-01 - 2023-12-31	\$378.93	EA	
Y	00006-0112-54	2023-01-01 - 2023-12-31	\$1,129.95	EA	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code (NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	00006-0221-28	2023-01-01 - 2023-12-31	\$1,236.69	EA	
Y	00006-0221-31	2023-01-01 - 2023-12-31	\$377.95	EA	
Y	00006-0221-54	2023-01-01 - 2023-12-31	\$1,135.85	EA	
Y	00006-0277-28	2023-01-01 - 2023-12-31	\$1,207.20	EA	
Y	00006-0277-31	2023-01-01 - 2023-12-31	\$379.25	EA	
Y	00006-0277-54	2023-01-01 - 2023-12-31	\$1,128.75	EA	
Y	00006-0277-82	2023-01-01 - 2023-12-31	\$12,648.35	EA	

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b)(3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.



The prices reported in Question 22 represent package prices for the NDC-11 indicated, whereas the Total Unit Volume represents Unit Type EA (tablets).

The total unit volumes reported in Question 22 are reported using the invoice date of each transaction. These values were current as of the date they were retrieved, which was in July 2023.

For calendar year 2023, Merck's reported Big Four Prices are effective through 12/31/2023; however, the units reported reflect 1Q2023 and 2Q2023 Big Four Federal purchases only.



G. Market Data and Revenue and Sales Volume Data						
U.S. Commercial Average Net Unit Price						
Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.						
National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-28	2018-Q3				EA	
00006-0221-31	2018-Q3				EA	
00006-0221-54	2018-Q3				EA	
00006-0112-28	2018-Q3				EA	
00006-0112-31	2018-Q3				EA	
00006-0112-54	2018-Q3				EA	
00006-0277-28	2018-Q3				EA	
00006-0277-31	2018-Q3				EA	
00006-0277-54	2018-Q3				EA	
00006-0277-82	2018-Q3				EA	
00006-0221-28	2018-Q4				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2018-Q4				EA	
00006-0221-54	2018-Q4				EA	
00006-0112-28	2018-Q4				EA	
00006-0112-31	2018-Q4				EA	
00006-0112-54	2018-Q4				EA	
00006-0277-28	2018-Q4				EA	
00006-0277-31	2018-Q4				EA	
00006-0277-54	2018-Q4				EA	
00006-0277-82	2018-Q4				EA	
00006-0221-28	2019-Q1				EA	
00006-0221-31	2019-Q1				EA	
00006-0221-54	2019-Q1				EA	
00006-0112-28	2019-Q1				EA	
00006-0112-31	2019-Q1				EA	
00006-0112-54	2019-Q1				EA	
00006-0277-28	2019-Q1				EA	
00006-0277-31	2019-Q1				EA	
00006-0277-54	2019-Q1				EA	
00006-0277-82	2019-Q1				EA	
00006-0221-28	2019-Q2				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2019-Q2				EA	
00006-0221-54	2019-Q2				EA	
00006-0112-28	2019-Q2				EA	
00006-0112-31	2019-Q2				EA	
00006-0112-54	2019-Q2				EA	
00006-0277-28	2019-Q2				EA	
00006-0277-31	2019-Q2				EA	
00006-0277-54	2019-Q2				EA	
00006-0277-82	2019-Q2				EA	
00006-0221-28	2019-Q3				EA	
00006-0221-31	2019-Q3				EA	
00006-0221-54	2019-Q3				EA	
00006-0112-28	2019-Q3				EA	
00006-0112-31	2019-Q3				EA	
00006-0112-54	2019-Q3				EA	
00006-0277-28	2019-Q3				EA	
00006-0277-31	2019-Q3				EA	
00006-0277-54	2019-Q3				EA	
00006-0277-82	2019-Q3				EA	
00006-0221-28	2019-Q4				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2019-Q4				EA	
00006-0221-54	2019-Q4				EA	
00006-0112-28	2019-Q4				EA	
00006-0112-31	2019-Q4				EA	
00006-0112-54	2019-Q4				EA	
00006-0277-28	2019-Q4				EA	
00006-0277-31	2019-Q4				EA	
00006-0277-54	2019-Q4				EA	
00006-0277-82	2019-Q4				EA	
00006-0221-28	2020-Q1				EA	
00006-0221-31	2020-Q1				EA	
00006-0221-54	2020-Q1				EA	
00006-0112-28	2020-Q1				EA	
00006-0112-31	2020-Q1				EA	
00006-0112-54	2020-Q1				EA	
00006-0277-28	2020-Q1				EA	
00006-0277-31	2020-Q1				EA	
00006-0277-54	2020-Q1				EA	
00006-0277-82	2020-Q1				EA	
00006-0221-28	2020-Q2				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2020-Q2				EA	
00006-0221-54	2020-Q2				EA	
00006-0112-28	2020-Q2				EA	
00006-0112-31	2020-Q2				EA	
00006-0112-54	2020-Q2				EA	
00006-0277-28	2020-Q2				EA	
00006-0277-31	2020-Q2				EA	
00006-0277-54	2020-Q2				EA	
00006-0277-82	2020-Q2				EA	
00006-0221-28	2020-Q3				EA	
00006-0221-31	2020-Q3				EA	
00006-0221-54	2020-Q3				EA	
00006-0112-28	2020-Q3				EA	
00006-0112-31	2020-Q3				EA	
00006-0112-54	2020-Q3				EA	
00006-0277-28	2020-Q3				EA	
00006-0277-31	2020-Q3				EA	
00006-0277-54	2020-Q3				EA	
00006-0277-82	2020-Q3				EA	
00006-0221-28	2020-Q4				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2020-Q4				EA	
00006-0221-54	2020-Q4				EA	
00006-0112-28	2020-Q4				EA	
00006-0112-31	2020-Q4				EA	
00006-0112-54	2020-Q4				EA	
00006-0277-28	2020-Q4				EA	
00006-0277-31	2020-Q4				EA	
00006-0277-54	2020-Q4				EA	
00006-0277-82	2020-Q4				EA	
00006-0221-28	2021-Q1				EA	
00006-0221-31	2021-Q1				EA	
00006-0221-54	2021-Q1				EA	
00006-0112-28	2021-Q1				EA	
00006-0112-31	2021-Q1				EA	
00006-0112-54	2021-Q1				EA	
00006-0277-28	2021-Q1				EA	
00006-0277-31	2021-Q1				EA	
00006-0277-54	2021-Q1				EA	
00006-0277-82	2021-Q1				EA	
00006-0221-28	2021-Q2				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2021-Q2				EA	
00006-0221-54	2021-Q2				EA	
00006-0112-28	2021-Q2				EA	
00006-0112-31	2021-Q2				EA	
00006-0112-54	2021-Q2				EA	
00006-0277-28	2021-Q2				EA	
00006-0277-31	2021-Q2				EA	
00006-0277-54	2021-Q2				EA	
00006-0277-82	2021-Q2				EA	
00006-0221-28	2021-Q3				EA	
00006-0221-31	2021-Q3				EA	
00006-0221-54	2021-Q3				EA	
00006-0112-28	2021-Q3				EA	
00006-0112-31	2021-Q3				EA	
00006-0112-54	2021-Q3				EA	
00006-0277-28	2021-Q3				EA	
00006-0277-31	2021-Q3				EA	
00006-0277-54	2021-Q3				EA	
00006-0277-82	2021-Q3				EA	
00006-0221-28	2021-Q4				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2021-Q4				EA	
00006-0221-54	2021-Q4				EA	
00006-0112-28	2021-Q4				EA	
00006-0112-31	2021-Q4				EA	
00006-0112-54	2021-Q4				EA	
00006-0277-28	2021-Q4				EA	
00006-0277-31	2021-Q4				EA	
00006-0277-54	2021-Q4				EA	
00006-0277-82	2021-Q4				EA	
00006-0221-28	2022-Q1				EA	
00006-0221-31	2022-Q1				EA	
00006-0221-54	2022-Q1				EA	
00006-0112-28	2022-Q1				EA	
00006-0112-31	2022-Q1				EA	
00006-0112-54	2022-Q1				EA	
00006-0277-28	2022-Q1				EA	
00006-0277-31	2022-Q1				EA	
00006-0277-54	2022-Q1				EA	
00006-0277-82	2022-Q1				EA	
00006-0221-28	2022-Q2				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2022-Q2				EA	
00006-0221-54	2022-Q2				EA	
00006-0112-28	2022-Q2				EA	
00006-0112-31	2022-Q2				EA	
00006-0112-54	2022-Q2				EA	
00006-0277-28	2022-Q2				EA	
00006-0277-31	2022-Q2				EA	
00006-0277-54	2022-Q2				EA	
00006-0277-82	2022-Q2				EA	
00006-0221-28	2022-Q3				EA	
00006-0221-31	2022-Q3				EA	
00006-0221-54	2022-Q3				EA	
00006-0112-28	2022-Q3				EA	
00006-0112-31	2022-Q3				EA	
00006-0112-54	2022-Q3				EA	
00006-0277-28	2022-Q3				EA	
00006-0277-31	2022-Q3				EA	
00006-0277-54	2022-Q3				EA	
00006-0277-82	2022-Q3				EA	
00006-0221-28	2022-Q4				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2022-Q4				EA	
00006-0221-54	2022-Q4				EA	
00006-0112-28	2022-Q4				EA	
00006-0112-31	2022-Q4				EA	
00006-0112-54	2022-Q4				EA	
00006-0277-28	2022-Q4				EA	
00006-0277-31	2022-Q4				EA	
00006-0277-54	2022-Q4				EA	
00006-0277-82	2022-Q4				EA	
00006-0221-28	2023-Q1				EA	
00006-0221-31	2023-Q1				EA	
00006-0221-54	2023-Q1				EA	
00006-0112-28	2023-Q1				EA	
00006-0112-31	2023-Q1				EA	
00006-0112-54	2023-Q1				EA	
00006-0277-28	2023-Q1				EA	
00006-0277-31	2023-Q1				EA	
00006-0277-54	2023-Q1				EA	
00006-0277-82	2023-Q1				EA	
00006-0221-28	2023-Q2				EA	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price - Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
00006-0221-31	2023-Q2				EA	
00006-0221-54	2023-Q2				EA	
00006-0112-28	2023-Q2				EA	
00006-0112-31	2023-Q2				EA	
00006-0112-54	2023-Q2				EA	
00006-0277-31	2023-Q2				EA	
00006-0277-54	2023-Q2				EA	
00006-0277-82	2023-Q2				EA	
00006-0277-28	2023-Q2				EA	

Explanations: Response contains confidential and proprietary information that is exempt from disclosure under SSA § 1193(c), FOIA Exemptions 3 and 4 (5 USC § 552(b)(3-4)), 18 USC § 1905, and CMS guidance § 40.2.1.

[Redacted]

[Redacted] This price is defined as “the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange,” excluding certain types of plans. [Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

The ICR instructions specifically require “U.S. Commercial Average Net Unit Price – Without Patient Assistance Programs” to be calculated “net of manufacturer-run patient assistance programs that provide financial assistance such as coupons and co-payment assistance or free drug products to patients.”

[REDACTED]

[REDACTED]

Free goods provided to patients under the Merck patient assistance program are not offered by the responding entity; rather, such free goods are offered by the Merck Patient Assistance Program, Inc., a 501(c)(3) corporation.

[REDACTED]

[REDACTED]

Merck has not included the value of sample units consistent with the instructions to Question 24 or TRICARE Retail Pharmacy Refund Program sales.



Question	Sub-Question	Response
		<p>[REDACTED]</p> <p>[REDACTED]</p> <p>Prescribing information has been approved by the FDA for the selected drug, JANUVIA® (sitagliptin), [REDACTED] - indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2D. [REDACTED] Prescribing information for JANUVIA® (sitagliptin) is available at https://www.merck.com/product/usa/pi_circulars/j/januvia/januvia_pi.pdf</p> <p>[REDACTED]</p> <p>Based on the evidence-based guidelines from the American Diabetes Association (ADA), pharmacotherapy should be initiated after implementation of healthy lifestyle modification behaviors, and diabetes self-management education and support.(15) The goal of pharmacotherapy is to achieve and maintain adequate HbA1c as per individualized treatment goals through either single or add-on drug therapy.(16) Current and former guidelines generally suggest metformin as the preferred initial pharmacotherapy for helping patients with T2D achieve glycemic goals, (15, 17) and supplementing therapy with other glucose lowering medications (GLMs) with alternate mechanisms of actions as needed to help achieve HbA1c targets.(15, 18, 19)</p> <p>Choice of initial monotherapy or add-on therapy should be guided by physician-determined clinical characteristics, individual patient preferences, and patient-centered factors.(15) Examples of these factors include individualized glycemic goals, impact on weight, risk of hypoglycemia, cardiorenal protection, underlying physiologic factors, side effect profiles of medications, complexity of regimen, regimen choice to optimize medication use and reduce treatment discontinuation, mental acuity and other co-morbidities that may be impacted by GLMs or make some GLM’s more difficult for the patient to correctly use.(15, 20)</p> <p>[REDACTED]</p>



Question	Sub-Question	Response
		<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED] Landon et al., using the Master Beneficiary Summary File, a random 20% sample of beneficiary complete claims and prescription claims data from the Part D files, analyzed choices of first GLMs and patterns of adding additional medications in patients with diabetes between 2007 and 2014.(27) While use of metformin was directly reported, results for all other initial and second medication choices were categorized by class of drug for sulfonylureas, thiazolidinediones and insulin. DPP-4is, GLP-1RAs, and SGLT-2is were reported only as a group of “Other” agents. The authors determined that metformin was the most common first agent, with sulfonylureas being the second most common first agent. When metformin was the initial agent, a sulfonylurea was the most common second agent, and when a sulfonylurea was the initial agent, metformin was the most common second agent. The group of “Other” agents that include DPP-4is [REDACTED] [REDACTED] were used as an additional agent to metformin or sulfonylureas in 25.9% and 17.4% of patients, respectively.</p> <p>Over time, the use of DPP-4is, SGLT-2is and GLP-1RAs has grown. McCoy et al. conducted a retrospective cohort study to examine the trends in initiation of GLP-1RA, SGLT-2i, and DPP-4i treatment among Medicare Advantage and commercial health plan beneficiaries with T2D aged 58 to 66 years from 2016 to 2019.(28) McCoy et al. also looked at GLP-1RAs, SGLT-2is, and DPP-4is as classes and not at the individual product level. [REDACTED]</p> <p>[REDACTED] The authors determined that metformin was again the most common first agent; however, the rate of initiation of other drug classes, such as SGLT-2is, GLP-1RAs, and DPP-4is, as second agents grew over the period. In Medicare Advantage beneficiaries the initiation of SGLT-2is grew from 1.57% to 8.51%, GLP-1RAs grew from 1.50% to 11.44%, and DPP-4is grew from 2.44% to 7.68%. [REDACTED]</p> <p>References for Question 27:</p>



Question	Sub-Question	Response
		<div style="background-color: black; width: 100%; height: 100%; min-height: 200px; position: relative;"> <div style="position: absolute; top: 0; right: 0; width: 100%; height: 100%; opacity: 0.5;"></div> </div> <p>15. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. <i>Diabetes Care</i>. 2023;46:S140-S57. doi: 10.2337/dc23-S009. PubMed PMID: WOS:000905206200011.</p> <p>16. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. Glycemic Targets: Standards of Care in Diabetes-2023. <i>Diabetes Care</i>. 2023;46(Suppl 1):S97-S110. doi: 10.2337/dc23-S006. PubMed PMID: 36507646; PubMed Central PMCID: PMC9810469.</p> <p>17. American Diabetes Association (7) Approaches to glycemic treatment. <i>Diabetes Care</i>. 2015;38 Suppl:S41-8. doi: 10.2337/dc15-S010. PubMed PMID: 25537707.</p> <p>18. Desai U, Kirson NY, Kim J, Khunti K, King S, Trieschman E, et al. Time to Treatment Intensification After Monotherapy Failure and Its Association With Subsequent Glycemic Control Among 93,515 Patients With Type 2 Diabetes. <i>Diabetes Care</i>. 2018;41(10):2096-104. Epub 20180821. doi: 10.2337/dc17-0662. PubMed PMID: 30131396.</p> <p>19. Pantalone KM, Wells BJ, Chagin KM, Ejzykowicz F, Yu C, Milinovich A, et al. Intensification of Diabetes Therapy and Time Until A1C Goal Attainment Among Patients With Newly Diagnosed Type 2 Diabetes Who Fail Metformin Monotherapy Within a Large Integrated Health System. <i>Diabetes Care</i>. 2016;39(9):1527-34. Epub 20160812. doi: 10.2337/dc16-0227. PubMed PMID: 27519447.</p> <p>20. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. Older Adults: Standards of Care in Diabetes-2023. <i>Diabetes Care</i>. 2023;46(Suppl 1):S216-S29. doi: 10.2337/dc23-S013. PubMed PMID: 36507638; PubMed Central PMCID: PMC9810468.</p> <div style="background-color: black; width: 100%; height: 100%; min-height: 150px; position: relative;"> <div style="position: absolute; top: 0; right: 0; width: 100%; height: 100%; opacity: 0.5;"></div> </div>



Question	Sub-Question	Response
		<p>[REDACTED]</p> <p>27. Landon BE, Zaslavsky AM, Souza J, Ayanian JZ. Trends in Diabetes Treatment and Monitoring among Medicare Beneficiaries. <i>J Gen Intern Med.</i> 2018;33(4):471-80. doi: 10.1007/s11606-018-4310-4. PubMed PMID: WOS:000428999600017.</p> <p>28. McCoy RG, Van Houten HK, Deng Y, Mandic PK, Ross JS, Montori VM, et al. Comparison of Diabetes Medications Used by Adults With Commercial Insurance vs Medicare Advantage, 2016 to 2019. <i>JAMA Netw Open.</i> 2021;4(2):e2035792. Epub 20210201. doi: 10.1001/jamanetworkopen.2020.35792. PubMed PMID: 33523188; PubMed Central PMCID: PMC7851726.</p> <p>[REDACTED]</p>
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	<p>Key Outcomes</p> <p>Sitagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2D).(1) The efficacy of glucose-lowering medications (GLMs) [REDACTED] may be defined by their ability to reduce blood glucose levels. Glycemic control can be assessed by monitoring hemoglobin A1c (HbA1c).(2) HbA1c provides a measure of average glycemia over approximately 3 months</p>



Question	Sub-Question	Response
		<p>and is used in clinical trials to demonstrate glycemic control.(2) Reductions in HbA1c are associated with a reduction in risk of diabetes-associated microvascular and macrovascular complications (3, 4), thus the goal of therapy in many adults is to reduce HbA1c to <7.0% without significant hypoglycemia.(2)</p> <p>Sitagliptin as a Therapeutic Advance and its Therapeutic Alternative</p> <p>Sitagliptin, approved in the U.S. in 2006 as the first in the class of dipeptidyl peptidase-4 inhibitors (DPP-4is),(5) was a therapeutic advance in treating T2D. As a new mechanism of action, physicians and patients have a new treatment option for use as monotherapy or in addition to other agents. Sitagliptin alone(6, 7) or added-on to metformin(8-10) effectively lowers HbA1c, has a low incidence of hypoglycemia and, after dose adjustment, can be used in patients with renal impairment.(1) DPP-4is were first highlighted in the ADA guidelines in 2012.(11) [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>Sitagliptin can be used as monotherapy. Aschner et al. conducted a randomized, double-blind, placebo-controlled trial to explore tolerability and efficacy in patients with inadequately controlled T2D.(6) 741 patients were randomized to once daily sitagliptin 100mg or 200mg or placebo (1:1:1) for 24 weeks. Baseline HbA1c was 8.0%. Sitagliptin 100mg and 200mg achieved a placebo-adjusted reduction in HbA1c of -0.79%[95% CI -0.96 to -0.62] and -0.94%[-1.11 to -0.77], respectively. Patients with higher baseline HbA1c's tended to have a greater reduction. Patients given sitagliptin 100mg with baseline HbA1c's of ≥9% or higher had reductions in HbA1c of -1.52%, those with ≥8% but <9% had reductions in HbA1c of -0.8% and those with <8% had -0.57% reductions in HbA1c.</p>



Question	Sub-Question	Response
		<p>Sitagliptin can be added to metformin for additional reduction in HbA1c. Charbonnel et al. studied the addition of once daily sitagliptin 100mg to metformin ≥ 1500mg/day for 24 weeks in patients with a mean HbA1c of 8.0%.⁽⁸⁾ Sitagliptin use resulted in a placebo-adjusted reduction in HbA1c of -0.65%. In Scott et al., patients with a mean baseline HbA1c of 7.7% on metformin ≥ 1500mg/day were randomized to placebo, rosiglitazone 8mg/day or sitagliptin 100mg/day for 18 weeks.⁽¹⁰⁾ These patients achieved a reduction in HbA1c from baseline, of -0.22%, -0.79% and -0.75% respectively. The proportion of patients who achieved a HbA1c of $< 7.0\%$ was 38%, 63% and 55% for placebo, rosiglitazone, and sitagliptin, respectively. In Raz et al., patients with a mean HbA1c of 9.2% on metformin ≥ 1500mg/day and randomized to add sitagliptin 100mg/day or placebo achieved a placebo-adjusted reduction in HbA1c of -1.0% at both 18 and 30-weeks, and 22.1% of patients achieved HbA1c below 7.0%.⁽⁹⁾</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>The Institute of Medicine defines comparative effectiveness research as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care”.⁽¹⁷⁾ [REDACTED]</p> <p>[REDACTED]</p>



Question	Sub-Question	Response
		[Redacted]



Question	Sub-Question	Response
		[REDACTED]



Question	Sub-Question	Response
		[Redacted]



Question	Sub-Question	Response
		<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>Conclusions</p> <p>[REDACTED] Sitagliptin alone(6, 7) or added-on to metformin(8-10) effectively lowers HbA1c, has a low incidence of hypoglycemia, has a neutral impact on body weight, and after dose adjustment may be used in patients with renal impairment.(1)</p> <p>[REDACTED]</p>



Question	Sub-Question	Response
		<p>[REDACTED]</p> <p>Clinical appropriateness of a treatment option for an individual patient is determined by the healthcare provider. [REDACTED]</p> <p>[REDACTED] The ADA guidelines recommend patients and physicians choose GLMs based upon individual treatment needs.(14) [REDACTED]</p> <p>[REDACTED]</p>
	<p>Hyperlink to Citation - Additional Materials for Question 28</p>	<p>[REDACTED]</p>
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28</p>	<p>[REDACTED]</p>
	<p>Evidence Submitted include a cost-effectiveness measure?</p>	<p>N</p>
	<p>What type of Evidence is shown?</p>	<p>[REDACTED]</p>
<p>Question 29: Comparative Effectiveness on Specific Populations</p>	<p>Response to Question 29</p>	<p>[REDACTED]</p> <p>The Institute of Medicine defines comparative effectiveness research as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care”.(1) [REDACTED]</p> <p>[REDACTED]</p>



Question	Sub-Question	Response
		[REDACTED]
[REDACTED]		
[REDACTED]		



Question	Sub-Question	Response
		[REDACTED]



Question	Sub-Question	Response
		[Redacted]



Question	Sub-Question	Response
		[Redacted]
		[Redacted]
		[Redacted]



Question	Sub-Question	Response
		[REDACTED]



Question	Sub-Question	Response
		<p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p>
	Hyperlink to Citation - Additional Materials for Question 29	<p>[Redacted]</p>



Question	Sub-Question	Response
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29</p>	<p>[REDACTED]</p>
	<p>Evidence Submitted include a cost-effectiveness measure?</p>	<p>N</p>
	<p>What type of Evidence is shown?</p>	
<p>Question 30: Addressing Unmet Medical Needs</p>	<p>Response to Question 30</p>	<p>Unmet Medical Need</p> <p>Despite the wide variety of treatment options available, data illustrates that there is an unmet medical need for multiple treatment options for patients with Type 2 Diabetes (T2D) to help them meet their individual treatment goals. According to a 2021 analysis of the 1999-2018 National Health and Nutrition Examination Survey, less than 70% of patients with diabetes in the U.S. were achieving their individualized hemoglobin A1c (HbA1c) targets between 2015 and 2018.(1) The mean HbA1c was 7.62% in 1999-2002, dropping to a low of 7.11% in 2007-2010 and 7.32% in 2015-2018. These results were seen even though 82.7% of patients were receiving one or more glucose lowering medications (GLMs). [REDACTED]</p> <p>Meeting the Unmet Medical Need for Type 2 Diabetes</p> <p>Management of T2D requires an individualized and patient-centered approach.(2) After receiving a T2D diagnosis, patient efforts at modifying lifestyle factors are often not consistent with recommendations.(3) Thus, the use of GLMs is common. The goal of pharmacotherapy with GLMs is to achieve and maintain adequate glycosylated HbA1c as per the patient’s individualized treatment goals.(4) The concomitant use of multiple GLMs is common,(5) and use of early</p>



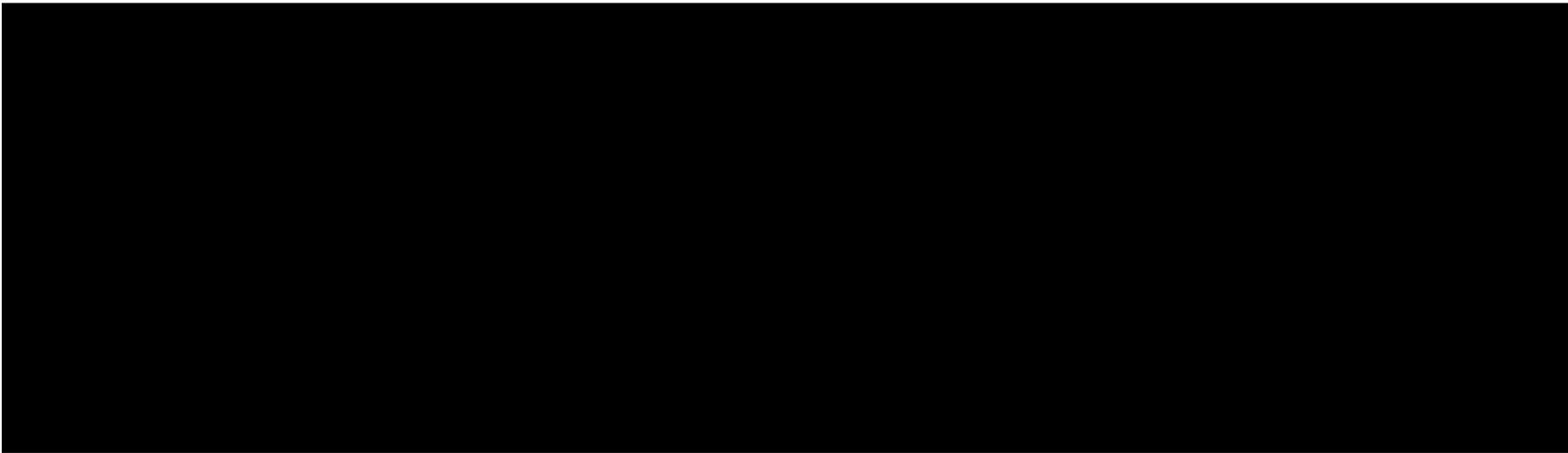
Question	Sub-Question	Response
		<p>[REDACTED]</p>
	Hyperlink to Citation - Additional Materials for Question 30	<p>[REDACTED]</p>
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	<p>[REDACTED]</p>
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	

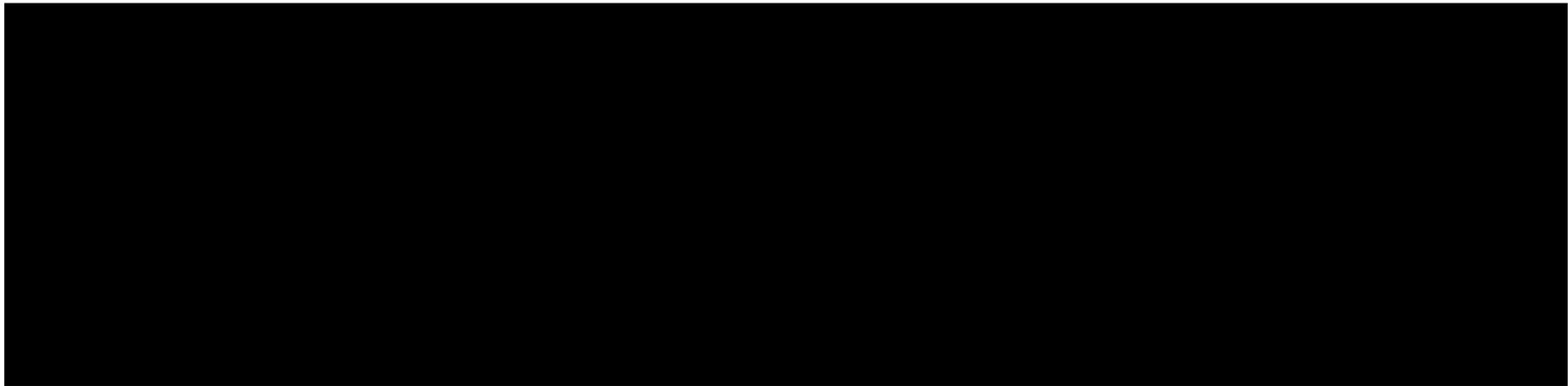


Question	Sub-Question	Response
		[REDACTED]
[REDACTED]		



Question	Sub-Question	Response
		[Redacted]





Question 28:

1. 1. Merck, Sharpe & Dohme, LLC. JANUVIA (sitagliptin) prescribing information; 2023 [Revised 7/2023]. Available from: https://www.merck.com/product/usa/pi_circulars/j/januvia/januvia_pi.pdf.
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6. 6. Aschner P, Kipnes MS, Lunceford JK, Sanchez M, Mickel C, Williams-Herman DE, et al. Effect of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy on glycemic control in patients with type 2 diabetes. *Diabetes Care*. 2006;29(12):2632-7. doi: 10.2337/dc06-0703. PubMed PMID: 17130196.
7. 7. Raz I, Hanefeld M, Xu L, Caria C, Williams-Herman D, Khatami H, et al. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy in patients with type 2 diabetes mellitus. *Diabetologia*. 2006;49(11):2564-71. Epub 20060926. doi: 10.1007/s00125-006-0416-z. PubMed PMID: 17001471.
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11. 11. Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2012;35(6):1364-79. Epub 20120419. doi: 10.2337/dc12-0413. PubMed PMID: 22517736; PubMed Central PMCID: PMC3357214.
12. [REDACTED]

13.

14. 14. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. Diabetes Care. 2023;46:S140-S57. doi: 10.2337/dc23-S009. PubMed PMID: WOS:000905206200011.

15.

16.

17. 17. Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research. Washington, DC: Institute of Medicine; 2009.

18.

[Redacted text block]

Question 29:

1. Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research. Washington, DC: Institute of Medicine; 2009.

2. [Redacted text block]

[REDACTED]

Question 30:

1. Fang M, Wang D, Coresh J, Selvin E. Trends in Diabetes Treatment and Control in U.S. Adults, 1999-2018. *N Engl J Med.* 2021;384(23):2219-28. doi: 10.1056/NEJMsa2032271. PubMed PMID: 34107181; PubMed Central PMCID: PMC8385648.

2. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46:S140-S57. doi: 10.2337/dc23-S009. PubMed PMID: WOS:000905206200011.
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12. Raz I, Chen Y, Wu M, Hussain S, Kaufman KD, Amatruda JM, et al. Efficacy and safety of sitagliptin added to ongoing metformin therapy in patients with type 2 diabetes. *Curr Med Res Opin*. 2008;24(2):537-50. doi: 10.1185/030079908x260925. PubMed PMID: 18194595.

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15. [REDACTED]

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	SITAGLIPTIN
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	AARP
	Respondent Email Who is completing this form?	PAT
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
	Response to Question 29	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30 Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	

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Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	<p>AARP, which advocates for the more than 100 million Americans age 50 and over, is pleased to submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions. AARP commends CMS for soliciting feedback from the public and appreciates its efforts to ensure that patients, caregivers, and health care providers have a voice in the negotiation process. ..Data shows that brand-name drug prices have increased dramatically faster than inflation for decades. List prices for the 25 brand-name drugs with the highest total Medicare Part D spending in 2021 have increased by an average of 226% - or more than tripled - since they first entered the market. Data also shows that all but one of the top 25 drugs' lifetime price increases greatly exceeded the corresponding annual rate of general inflation (Consumer Price Index All Urban Consumers for All Items; CPI-U) over the period that each product has been on the market (i.e., product launch date until May 2023). For example, the price of Enbrel (Etanercept), used to treat rheumatoid arthritis and psoriatic arthritis, has increased by 701% since coming to market in 1998, and the price of Januvia (Sitagliptin), used to treat diabetes, has increased by 275% since entering the market in 2006. Further, the median price of a new brand-name prescription drug is now approximately \$200,000 per year, so even relatively small percentage price increases can translate into thousands of dollars and put life-saving medications out of reach of the patients who need them...High prescription drug prices can negatively affect older adults' health and financial security. [REDACTED], a Medicare enrollee from [REDACTED], needs Januvia and Jardiance to treat a health condition. His out-of-pocket costs were upwards of \$400/month for Januvia and upwards of \$140/month for Jardiance. Within one billing cycle, [REDACTED] entered the Medicare "donut hole," and could not afford the out-of-pocket costs. "At the end of the day, I'm not going to do it. ... This issue is near and dear to me but also hacking me off." ..AARP fiercely believes that the needs of Medicare beneficiaries should remain paramount as the agency implements the Negotiation Program. In 2022, about 1 in 5 adults ages 65 and up either skipped, delayed, took less medication than was prescribed, or took someone else's medication last year because of concerns about cost. It is not fair or right to ask patients and taxpayers to continue paying for high prescription drug prices that are the result of broken markets. ..Successful implementation of the new federal law will help reduce prescription drug prices and costs and ensure that millions of older Americans are better able to access the prescription drugs they need at a price they can afford. The Medicare drug price negotiation process will also finally allow CMS to push back on indiscriminately escalating drug prices and ensure that taxpayer funds are paying for value – all while saving billions for Medicare and its beneficiaries. The CBO estimates that the Negotiation Program will save Medicare and the American taxpayers nearly \$98.5 billion over 10 years, reduce the budget deficit by \$25 billion in 2031, and save Medicare Part D enrollees \$7 billion in 2031 due to lower out-of-pocket costs and premiums. ..This is about real people whose lives are on the line. For decades, older Americans have paid the highest prices in the world for prescription drugs - often three times higher than people in other countries. Now is the time to change that. Effective implementation of this Program will represent a major victory for older Americans and their families across the country who are struggling to afford their prescriptions. It will also help encourage and appropriately reward the development of truly innovative</p>

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Question	Sub-Question	Response
		<p>products. AARP stands ready to assist in any way with these and other efforts to bring down drug prices and help older Americans afford the medications and treatments they need. If you have any questions, please do not hesitate to contact me or Gidget Benitez at gbenitez@aarp.org...Sincerely, ..Nancy LeaMond.Executive Vice President and Chief Advocacy & Engagement Officer</p>
Question 32: Executive Summary	Response to Question 32	



October 2, 2023

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Dear Dr. Seshamani:

AARP, which advocates for the more than 100 million Americans age 50 and over, is pleased to submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions. AARP commends CMS for soliciting feedback from the public and appreciates its efforts to ensure that patients, caregivers, and health care providers have a voice in the negotiation process.

Data shows that brand-name drug prices have increased dramatically faster than inflation for decades. List prices for the 25 brand-name drugs with the highest total Medicare Part D spending in 2021 have increased by an average of 226%—or more than tripled—since they first entered the market.¹ Data also shows that all but one of the top 25 drugs' lifetime price increases greatly exceeded the corresponding annual rate of general inflation (Consumer Price Index All Urban Consumers for All Items; CPI-U) over the period that each product has been on the market (i.e., product launch date until May 2023).² For example, the price of Enbrel (Etanercept), used to treat rheumatoid arthritis and psoriatic arthritis, has increased by 701% since coming to market in 1998, and the price of Januvia (Sitagliptin), used to treat diabetes, has increased by 275% since entering the market in 2006.³ Further, the median price of a new brand-name prescription drug is now approximately \$200,000 per year,⁴ so even relatively small percentage price increases can translate into thousands of dollars and put life-saving medications out of reach of the patients who need them.

High prescription drug prices can negatively affect older adults' health and financial security. [REDACTED], a Medicare enrollee from [REDACTED], needs Januvia and Jardiance to treat a health condition. His out-of-pocket costs were upwards of \$400/month for Januvia and upwards of \$140/month for Jardiance. Within one billing cycle, [REDACTED] entered the Medicare "donut hole," and could not afford the out-of-pocket costs. "At the end of the day, I'm not going to do it. ... This issue is near and dear to me but also hacking me off."

¹ Leigh Purvis, "Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market." Washington, DC: AARP Public Policy Institute, August 10, 2023. <https://doi.org/10.26419/ppi.00202.001>.

² *Id.*

³ *Id.*

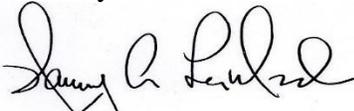
⁴ Benjamin N. Rome, Alexander C. Egilman, and Aaron S. Kesselheim, "Trends in Prescription Drug Launch Prices, 2008–2021," *Journal of the American Medical Association* 327, no. 21 (2022): 2145–47, <https://jamanetwork.com/journals/jama/fullarticle/2792986>; Deena Beasley, "U.S. New Drug Price Exceeds \$200,000 Median in 2022," Reuters, January 5, 2023, <https://www.reuters.com/business/healthcare-pharmaceuticals/us-new-drug-price-exceeds-200000-median-2022-2023-01-05/>.

AARP fiercely believes that the needs of Medicare beneficiaries should remain paramount as the agency implements the Negotiation Program. In 2022, about 1 in 5 adults ages 65 and up either skipped, delayed, took less medication than was prescribed, or took someone else's medication last year because of concerns about cost.⁵ It is not fair or right to ask patients and taxpayers to continue paying for high prescription drug prices that are the result of broken markets.

Successful implementation of the new federal law will help reduce prescription drug prices and costs and ensure that millions of older Americans are better able to access the prescription drugs they need at a price they can afford. The Medicare drug price negotiation process will also finally allow CMS to push back on indiscriminately escalating drug prices and ensure that taxpayer funds are paying for value – all while saving billions for Medicare and its beneficiaries. The CBO estimates that the Negotiation Program will save Medicare and the American taxpayers nearly \$98.5 billion over 10 years,⁶ reduce the budget deficit by \$25 billion in 2031,⁷ and save Medicare Part D enrollees \$7 billion in 2031 due to lower out-of-pocket costs and premiums.⁸

This is about real people whose lives are on the line. For decades, older Americans have paid the highest prices in the world for prescription drugs - often three times higher than people in other countries. Now is the time to change that. Effective implementation of this Program will represent a major victory for older Americans and their families across the country who are struggling to afford their prescriptions. It will also help encourage and appropriately reward the development of truly innovative products. AARP stands ready to assist in any way with these and other efforts to bring down drug prices and help older Americans afford the medications and treatments they need. If you have any questions, please do not hesitate to contact me or Gidget Benitez at gbenitez@aarp.org.

Sincerely,



Nancy A. LeaMond
Executive Vice President and
Chief Advocacy & Engagement Officer

⁵ Stacie B. Dusetzina et al., “Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022,” *JAMA Network Open* 6, no. 5 (2023): e2314211, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012>.

⁶ Congressional Budget Office, “Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14.” https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf. Accessed September 27, 2023.

⁷ Congressional Budget Office, “How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act.” <https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf>. Accessed September 27, 2023.

⁸ *Id.*

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	SITAGLIPTIN
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Aimed Alliance
	Respondent Email Who is completing this form?	PAO
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
	Response to Question 29	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30 Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	

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Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	



September 28, 2023

Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: IRA Patient Listening Sessions

Dear Administrator Brooks-LaSure:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to express our concerns with the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions.

While we support efforts aimed at making prescription drugs more affordable for Medicare Part D beneficiaries, Aimed Alliance strongly urges the Centers for Medicare & Medicaid Services (CMS) to ensure the patient voice and perspective is valued in a genuine, long-term, and sustainable manner.

I. Background

In August 2022, Congress passed the IRA, which provided CMS the authority to directly negotiate the prices of certain prescription drugs with drug manufacturers.¹ The negotiations are limited to single source drugs, without generic or biosimilar alternatives, that have been on the market for at least 7 years, or 11 years for biologics.² On August 29, 2023, CMS published a list of 10 prescription drugs that are subject to the Medicare negotiation process. These drugs cover treatments for cardiovascular diseases, diabetes, chronic kidney disease, psoriasis, rheumatoid arthritis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.³ CMS stated these drugs were identified as the ten most expensive covered Part D drugs.

In determining the negotiated price CMS will impose, CMS stated it will consider various factors, including comparative effectiveness and impact on specific populations, such as individuals with disabilities, the elderly, terminally ill patients, children, and others; and the extent to which the drug and its alternatives address an unmet medical need.⁴ Aimed Alliance urges CMS to ensure patient and provider lived experiences are adequately valued when considering these factors and throughout this process.

¹ CMS, *Fact Sheet: Key Information on the Process for the First Round of Negotiations for the Medicare Drug Price Negotiation Program*, <https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf>

² *Id.*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>

³ *Id.*

⁴ <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>

II. Appropriately Value Patient and Provider Lived Experiences

Aimed Alliance applauds CMS for incorporating patient and provider lived experiences in the drug negotiation process. However, we urge CMS to expand the current process to ensure a wider network of patients and providers can participate, and to guarantee patient and provider voices are genuinely valued.

Internationally, several countries employ mechanisms that allow governments to negotiate drug prices with manufacturers. For example, France and Sweden base drug pricing on factors such as therapeutic value, the price of comparable treatments, and the contributions of the drug's sales to the national economy.⁵ Sweden further incorporates ethical considerations, prioritizing those with the greatest health care needs and ensuring the process upholds and respects individual human dignity.⁶ By valuing the needs of patients and providers, Sweden maintains an overall high health care satisfaction rate.⁷ In contrast, the United Kingdom, which also implements a government negotiation program, has seen reports of patients being unable to access innovative treatments that may improve their condition and quality of life due to non-patient-centered valuations.⁸ As a result of failing to appropriately value patient-perspectives on the benefits of treatments, patients in the United Kingdom also experience reduced uptake of new cancer treatments.⁹

Ultimately, while various systems have provided means to center patient-perspectives and lived experiences, not all systems genuinely value these insights in determining drug prices, ultimately impacting treatment accessibility. Aimed Alliance urges CMS to properly value the lived experiences of patients, providers, and caregivers, and recognize the benefits these treatments provide to consumer's health and quality of life.

III. Expand the Number of Listening Sessions to Ensure Diverse Representation

Under the current framework, CMS offers only one listening session for each selected prescription drug, with each session lasting less than two hours and accommodating only 20 in-person speakers. Members of the public who are not selected to speak also have the option to submit written comments.¹⁰ Aimed Alliance urges CMS to expand the number of listening

⁵ David J. Gross, Jonathan Ratner, James Perez & Sarah Glavin, *International Pharmaceutical Controls: France, Germany, Sweden, and the United Kingdom*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193451/#:~:text=New%20product%20prices%20emerge%20from,sales%20to%20the%20national%20economy>.

⁶ Global Legal Rights, *Pricing & Reimbursement Laws and Regulations 2023*,

<https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/sweden>

⁷ Roosa Tikkanen, et al., *Sweden Scorecard*, <https://www.commonwealthfund.org/international-health-policy-center/countries/sweden>; Ketevan Kandelaki, *Patient-centeredness as a quality domain in Swedish healthcare: results from the first national surveys in difference Swedish health care setting*, <https://bmjopen.bmj.com/content/6/1/e009056>.

⁸ Houses of Parliament: Parliamentary Office of Science & Technology, *Drug Pricing*, https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf

⁹ *Id.*

¹⁰ CMS, *Medicare Drug Price Negotiations Program Patient-Focused Listening Sessions*, <https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions>

sessions to ensure patients, organizations, and caregivers have the opportunity to speak on behalf of their communities.

The 20 speakers selected to participate in each session are requested to address patients' day-to-day experiences living with their condition and under their treatment; the benefits and side effects of the treatments; patient access, adherence, and affordability; and any additional information the speaker considers significant.¹¹ While Aamed Alliance believes this information is crucial for appropriately determining the negotiated prices, we are concerned that relying on 20 randomly selected speakers will not provide CMS with a comprehensive perspective on these medications and their benefits to patients, providers, and caregivers. We are also concerned that this random selection process could unintentionally exclude speakers who shed light on health equity, minority health, and other access issues.¹² Therefore, we urge CMS to expand the number of listening sessions to ensure CMS appropriately considers the broad implications and health equity considerations of these treatments; and how these price negotiations could impact access for diverse communities.

Lastly, we strongly encourage CMS to value and give due consideration to both written and spoken comments provided by patient advocacy organizations. Individuals with chronic illnesses such as multiple sclerosis and inflammatory bowel disease (IBD) frequently experience social stigma, rejection, and workplace discrimination resulting from their condition.¹³ For instance, one study found that out of 105 patients with IBD, 84 percent reported experiencing stigma associated with their condition.¹⁴ Consequently, it is critical to recognize that some individuals with chronic conditions may not feel comfortable discussing their health, treatments, and challenges openly. As a result, they often rely on advocacy organizations to share their stories, perspectives, and experiences.

IV. Conclusion

In conclusion, we sincerely appreciate the opportunity to provide feedback on the IRA process and CMS's efforts to ensure the voices of patients, providers, and caregivers are at the forefront of this process. Please contact us at policy@aimedalliance.org if you have any additional questions.

Sincerely,
Ashira Vantrees
Counsel

¹¹ *Id.*

¹² Khiara Bridges, *Implicit Bias and Racial Disparities in Health Care*, https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/racial-disparities-in-health-care/

¹³ Valerie A Earnshaw, Diane M. Quinn & Crystall L. Park, *Anticipated stigma and quality of life among people living with chronic illnesses*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3644808/>

¹⁴ Marco Vinezco Lenti, et al., *Stigmatization and resilience in inflammatory bowel disease patients at one-year follow up*, <https://www.frontiersin.org/articles/10.3389/fgstr.2022.1063325/full>

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	SITAGLIPTIN
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Chronic Care Policy Alliance
	Respondent Email	
Question 27: Prescribing Information	Who is completing this form?	PAO
	Prescribing Information	The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...As CMS weighs information on how this product is prescribed and factors that information into the negotiation process, CMS should ensure that the negotiated price continues to support the patients using the product and their current usage. Patients using the product off-label or in different doses than the label should continue to have the same access after the negotiation process. Additionally, ensuring that the negotiation does not spur greater restrictions to access or utilization management, is also important to patients.
	Evidence Submitted include a cost-effectiveness measure?	N
Question 28: Therapeutic Impact and Comparative Effectiveness	What type of Evidence is shown?	
	Therapeutic Impact and Comparative Effectiveness	The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...As CMS weighs information on the therapeutic impact and comparative effectiveness of this product, it is paramount that CMS recognize that individual patients may experience substantial benefit from a product that may not be apparent in aggregated data. Because of this, as CMS considers how this area factors into the overall price negotiation, CMS should ensure a negotiated price reflects the value the product provides to each unique patient. CCPA believes it is important that the incentives to continue developing treatments for chronic diseases be preserved, and it is important to reward the value treatments bring to patients.

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Question	Sub-Question	Response
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28</p> <p>Evidence Submitted include a cost-effectiveness measure?</p> <p>What type of Evidence is shown?</p>	
<p>Question 29: Comparative Effectiveness on Specific Populations</p>	<p>Response to Question 29</p> <p>Hyperlink to Citation - Additional Materials for Question 29</p> <p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29</p> <p>Evidence Submitted include a cost-effectiveness measure?</p>	<p>The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...Patients with chronic diseases all have their own unique experiences – in considering comparative effectiveness, CMS should weigh equally the experiences of individuals the same as measurements of experiences of specific populations – in a way that elevates all voices, instead of letting larger voices outweigh single patients. CCPA also encourages CMS to take into account populations that may be uniquely adversely affected by negotiation, such as specific patient populations that may face new utilization or formulary restrictions. In this way, CMS can ensure that it pursues a patient-centered approach.</p>

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Question	Sub-Question	Response
	What type of Evidence is shown?	
	Response to Question 30	The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...CMS should ensure that its negotiation process on this product does not disadvantage any patient with an unmet medical need. Specifically, CMS should guard against the results of negotiations undercutting research into the product that may meet other unmet medical needs or may negatively impact the development of other products focused on unmet medical needs.
Question 30: Addressing Unmet Medical Needs	Hyperlink to Citation - Additional Materials for Question 30 Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30 Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	



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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	SITAGLIPTIN
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Diabetes Leadership Council
	Respondent Email Who is completing this form?	PAO
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	<p>On behalf of the Diabetes Leadership Council (DLC), thank you for the opportunity to provide patient-focused comments on four diabetes therapies included in the first 10 Medicare Part D drugs that the Centers for Medicare & Medicaid Services (CMS) selected for price negotiation. ..DLC unites former leaders of national diabetes organizations who are dedicated to advancing patients-first policies. We are people with diabetes, parents of children with diabetes, allies and tireless volunteers dedicated to improving the lives of all people impacted by this condition. ..As advocates, we see first-hand how the diabetes community fares under an opaque and complex system that requires sick people to subsidize the healthy. Patients with chronic conditions like diabetes get stuck paying inflated costs for essential medicines under the false premise that it keeps costs lower for everyone else. People with diabetes shouldn't have to shoulder the burden for policymakers' failure to fix the dysfunctional drug pricing system. We write to urge CMS to consider the impact that its decisions will have on actual patients, and to underscore that price negotiations alone will not ensure affordable, equitable prescription drug access for Medicare beneficiaries. ..HIGH COST, HIGH UTILIZATION.Diabetes has a large and growing patient population and ranks among the top three therapy classes in terms of utilization and drug spend for both commercial insurance and Medicare. As evidenced by their overrepresentation on the initial list of drugs subject to price negotiation, diabetes therapies contribute to CMS costs not only due to price, but high volumes dispensed. The fact that four of the first ten therapies subject to negotiation are diabetes treatments also highlights the heavy toll of under-resourced and under-utilized prevention efforts in the face</p>

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Question Sub-Question

Response

of the diabetes epidemic. Nearly one-third of Medicare beneficiaries have diabetes and another 26.4 million people aged 65 years or older (48.8%) have prediabetes. CMS must ensure that its efforts produce tangible improvements in prescription drug access and affordability for beneficiaries managing diabetes today and in the future. ..ACCESS TO CARE.Diabetes is a highly competitive and heavily contracted category where discounts and rebates reduce net prices to levels much lower than gross or list prices. Diabetes medications already represent 42% of the \$48.6 billion in prescription drug rebates and discounts paid annually by Part D in the US. ..Beneficiary use of highly rebated or discounted drugs has different implications for plan sponsors, Medicare and patients. It can mean lower Medicare drug spending, as its plan sponsor payments are based on net drug costs after rebates. Individual beneficiary drug payments, however, may be based on the gross cost before accounting for rebates. The General Accounting Office (GAO) recently found payments by beneficiaries exceeded plan sponsor payments, after accounting for rebates, for 79 of the 100 drugs receiving the most rebate. Three therapeutic drug classes accounted for 73% of rebates: (1) endocrine metabolic agents, including antidiabetic drugs; (2) blood modifiers, including anti-stroke drugs; and (3) respiratory agents, including anti-asthma drugs. The same GAO report found instances where plan sponsors preferred rebated brand-name drugs with higher beneficiary costs over lower-cost alternatives. ..DIRECT PATIENT BENEFIT.Patients should directly benefit from drug prices negotiated on their behalf, whether negotiations are conducted by a government agency or commercial entity...CMS's price negotiations may be successful in extracting price concessions from manufacturers. Unfortunately, the program lacks any requirement to improve affordability and access for the very patients whose lives depend on these products. Instead, the program perpetuates the existing inequities that leave patients paying more for less while intermediaries pocket the savings. Patients who rely on the diabetes medications selected for price negotiations should see all rebates or discounts reflected in the price they pay at the pharmacy counter. ..Additionally, products subject to negotiated prices should be immediately added to Medicare formularies at the lowest cost-sharing tier and without utilization management or other barriers to appropriate use. Part D plans should encourage use of lower cost, therapeutically appropriate products by eliminating prior authorization, step therapy and other access barriers. ..Thank you for your consideration.

Hyperlink to
Table/Charts/Graphs -
Additional Materials for
Question 28
Evidence Submitted include
a cost-effectiveness
measure?

Public E2 Submission

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Question	Sub-Question	Response
	What type of Evidence is shown?	
Question 29: Comparative Effectiveness on Specific Populations	Response to Question 29	
	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	

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Question	Sub-Question	Response
	<p>Evidence Submitted include a cost-effectiveness measure?</p> <p>What type of Evidence is shown?</p>	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	<p>On behalf of the Diabetes Leadership Council (DLC), thank you for the opportunity to provide patient-focused comments on four diabetes therapies included in the first 10 Medicare Part D drugs that the Centers for Medicare & Medicaid Services (CMS) selected for price negotiation. ..DLC unites former leaders of national diabetes organizations who are dedicated to advancing patients-first policies. We are people with diabetes, parents of children with diabetes, allies and tireless volunteers dedicated to improving the lives of all people impacted by this condition. ..As advocates, we see first-hand how the diabetes community fares under an opaque and complex system that requires sick people to subsidize the healthy. Patients with chronic conditions like diabetes get stuck paying inflated costs for essential medicines under the false premise that it keeps costs lower for everyone else. People with diabetes shouldn't have to shoulder the burden for policymakers' failure to fix the dysfunctional drug pricing system. We write to urge CMS to consider the impact that its decisions will have on actual patients, and to underscore that price negotiations alone will not ensure affordable, equitable prescription drug access for Medicare beneficiaries. ..HIGH COST, HIGH UTILIZATION.Diabetes has a large and growing patient population and ranks among the top three therapy classes in terms of utilization and drug spend for both commercial insurance and Medicare. As evidenced by their overrepresentation on the initial list of drugs subject to price negotiation, diabetes therapies contribute to CMS costs not only due to price, but high volumes dispensed. The fact that four of the first ten therapies subject to negotiation are diabetes treatments also highlights the heavy toll of under-resourced and under-utilized prevention efforts in the face of the diabetes epidemic. Nearly one-third of Medicare beneficiaries have diabetes and another 26.4 million people aged 65 years or older (48.8%) have prediabetes. CMS must ensure that its efforts produce tangible improvements in prescription drug access and affordability for beneficiaries managing diabetes today and in the future. ..ACCESS TO CARE.Diabetes is a highly competitive and heavily contracted category where discounts and rebates reduce net prices to levels much lower than gross or list prices. Diabetes medications already represent 42% of the \$48.6 billion in prescription drug rebates and discounts paid annually by Part D in the US.</p>

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Question Sub-Question



Response

..Beneficiary use of highly rebated or discounted drugs has different implications for plan sponsors, Medicare and patients. It can mean lower Medicare drug spending, as its plan sponsor payments are based on net drug costs after rebates. Individual beneficiary drug payments, however, may be based on the gross cost before accounting for rebates. The General Accounting Office (GAO) recently found payments by beneficiaries exceeded plan sponsor payments, after accounting for rebates, for 79 of the 100 drugs receiving the most rebate. Three therapeutic drug classes accounted for 73% of rebates: (1) endocrine metabolic agents, including antidiabetic drugs; (2) blood modifiers, including anti-stroke drugs; and (3) respiratory agents, including anti-asthma drugs. The same GAO report found instances where plan sponsors preferred rebated brand-name drugs with higher beneficiary costs over lower-cost alternatives. ..DIRECT PATIENT BENEFIT. Patients should directly benefit from drug prices negotiated on their behalf, whether negotiations are conducted by a government agency or commercial entity...CMS's price negotiations may be successful in extracting price concessions from manufacturers. Unfortunately, the program lacks any requirement to improve affordability and access for the very patients whose lives depend on these products. Instead, the program perpetuates the existing inequities that leave patients paying more for less while intermediaries pocket the savings. Patients who rely on the diabetes medications selected for price negotiations should see all rebates or discounts reflected in the price they pay at the pharmacy counter. ..Additionally, products subject to negotiated prices should be immediately added to Medicare formularies at the lowest cost-sharing tier and without utilization management or other barriers to appropriate use. Part D plans should encourage use of lower cost, therapeutically appropriate products by eliminating prior authorization, step therapy and other access barriers. ..Thank you for your consideration.



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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	SITAGLIPTIN
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Pharmaceutical Care Management Association (PCMA)
	Respondent Email Who is completing this form?	
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	<p>The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments regarding the therapeutic alternatives for Sitagliptin. Our members help administer the Part D prescription drug benefit on behalf of many Part D plan sponsors, and a central component of that function is the identification of therapeutic alternatives to develop comprehensive prescription drug formularies consistent with applicable statutory, regulatory, and clinical requirements, including ensuring formularies are not discriminatory...In general, while we understand that CMS cannot disclose the specifics of their negotiations with manufacturers of selected drugs, we believe the public is best served by CMS disclosing as much about this process as possible, and otherwise aligning its methodology for selecting therapeutic alternatives with how Part D plans select therapeutic alternatives. Our comments focus on emphasizing the differences between identifying therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program, and the role that the identification of therapeutic alternatives plays under the Medicare Part D program's formulary standards and enrollee communication requirements. PCMA has three main points...1. As a general principle, CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for the Part D program. ...2. CMS should clarify in an HPMS memo to Part D plans that CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program will not impact the agency's existing approach towards evaluating Part D formulary design for compliance with Part D formulary requirements...3. CMS</p>

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should clarify in an HPMS memo that Part D plans retain discretion on how to communicate therapeutic alternatives to enrollees, and that CMS's identification of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program will not affect these enrollee communications...We discuss these issues in more detail below...I. CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for their formulary submissions. ..Currently, Part D plan sponsors consider a variety of factors when identifying therapeutic alternatives for their formulary submissions, including but not limited to (i) clinical effectiveness, (ii) safety, (iii) price, (iv) availability, and (v) patient preferences. Importantly, these factors are considered within a regulatory framework that imposes certain overarching formulary requirements. ..First, Part D plans must ensure that their formulary designs are nondiscriminatory. CMS considers several criteria when assessing whether a formulary is nondiscriminatory. CMS may presumptively approve formulary designs which align with the United States Pharmacopoeia's (USP) Medicare Model Guidelines (MMGs) based on the view that the MMGs reflect a scientifically and-clinically-based taxonomy developed by an independent expert body without a vested financial interest in the Part D program. The MMGs are also important because they provide a guiding framework for Part D plans to use when determining therapeutic alternatives. The MMGs group drugs into categories and classes. These categories and classes generally encompass the universe of potential therapeutic alternatives for a given medical condition. This means that Part D plans can use the MMGs to identify the range of therapeutic alternatives to consider when developing their formularies...Second, Part D plans must provide an adequate formulary, which among other things, means including at least two Part D drugs within a particular category or class of Part D drugs. This minimum formulary standard helps ensure a wide range of treatment options for enrollees, even if they have complex or rare medical conditions. Additionally, this requirement promotes patient choice and competition among drug manufacturers because the ability for patients to access alternative treatments incentivizes drug manufacturers to lower prices and innovate. The requirement to include at least two drugs per category or class helps to ensure that patients with a given medical condition have at least two formulary treatment options available to them, even if there are few therapeutic alternatives. This requirement is important because it prevents Part D plans from excluding entire categories or classes of drugs from their formularies...Third, Part D plans must consider cost sharing in the development of formularies. For example, CMS could raise concerns about formularies that place drugs on high cost-sharing tiers without placing therapeutic alternatives in preferable positions. CMS has also expressed concerns about "adverse tiering" where a plan sponsor assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high-cost medical condition to a high cost-sharing tier. In short, Part D plans must consider the enrollee's share of costs for a particular drug when considering therapeutic alternatives...PCMA encourages CMS to identify therapeutic alternatives for the Medicare Drug Price Negotiation Program in the same way that Part D plans do for their formularies. This would ensure consistency in process across two closely related programs and avoid introducing multiple, confusing standards for the same underlying definitional term. At the very least, aligning

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the selection of therapeutic alternatives under the Medicare Drug Price Negotiation Program with Part D formulary submissions would give Part D plans some assurance that CMS's assessment of their formulary submissions will not be affected by CMS's own process of selecting therapeutic alternatives...II. CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program should not compromise the agency's evaluation of the adequacy of Part D plan formulary design, ensuring that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs...PCMA acknowledges that CMS's identification of therapeutic alternatives under the Medicare Drug Price Negotiation Program is required by law and essential for successful drug pricing negotiations. As stated above, we urge CMS to attempt to align its selection of therapeutic alternatives with how Part D plans select therapeutic alternatives...That being said, it is important to recognize that the exercise of selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program and the Part D program, while overlapping in some areas, are ultimately distinct. Selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program requires unique considerations that are not fully applicable to how Part D plans identify and leverage therapeutic alternatives for formulary development. Accordingly, we do not expect CMS to perfectly align itself with Part D plan sponsor methodologies for selecting therapeutic alternatives.. .First, therapeutic alternatives are a statutory feature of the Medicare Drug Price Negotiation Program. CMS selects therapeutic alternatives when negotiating pricing for selected drugs because the statute requires the agency to do so. Even if the statute did not require CMS to identify therapeutic alternatives, CMS would likely need to do so because it supports the agency in carrying out its statutory mandate to negotiate a "maximum fair price" (MFP) with manufacturers. Importantly, the MFP applies in a vacuum without regards to affordability and relative competitiveness with other drugs that a beneficiary may access...By contrast, while Part D plans are required to select therapeutic alternatives for formulary submissions, Part D plans select therapeutic alternatives based on a delicate balance between clinical comparability, cost-effectiveness, and beneficiary access. Unlike CMS, which is required to focus on a single drug in isolation when assessing therapeutic alternatives, Part D plans, PBMs, and their pharmacy and therapeutics (P&T) committees are tasked with developing comprehensive formularies that holistically meet the complex needs of their enrollees. Part D plans must, already, cover selected drugs on their formularies under the statute, and CMS's interpretation worryingly suggests that such coverage may also involve a preferred status designation. Additional indirect restrictions on formulary design stemming from CMS's evaluation criteria under the Medicare Drug Price Negotiation Program could significantly hamper Part D plans' ability to offer competitive plan designs. In light of the comprehensive considerations that Part D plans must consider in developing formularies, CMS must ensure plans retain flexibility to adequately weigh all of these factors when developing formularies, including identifying therapeutic alternatives...Second, CMS's selection of therapeutic alternatives is a one-time event, done solely to determine the MFP for a selected drug. Once the MFP is determined, the drug's therapeutic alternatives play no further role in how Medicare beneficiaries access the selected drug...In contrast, a Part D plan sponsor's selection of therapeutic alternatives is used in multiple ways, including formulary design, coverage

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determination, tiering exceptions, and Part D appeals. This means that Part D plans must carefully consider all potential scenarios in which their selection of therapeutic alternatives may be challenged...Third, CMS's identification of therapeutic alternatives for purposes of the Drug Price Negotiation Program is nonpublic. CMS indicates in the Revised Guidance for the Medicare Drug Price Negotiation Program that the agency will not unilaterally disclose any information pertaining to its negotiations with manufacturers, including the therapeutic alternatives identified for such negotiations. As a result, Part D plans do not have access to the therapeutic alternatives that CMS identifies for selected drugs. It would be unfair and arbitrary for CMS to evaluate Part D plan formulary submissions, including the identification of therapeutic alternatives contained in the submission, on a criteria that CMS never releases to the public. Formulary guidelines like the USP Medicare Model Guidelines provide a more predictable basis for administering a prescription drug benefit than nonpublic information. ..In short, while we urge CMS to align its methodology for selecting therapeutic alternatives as much as possible with Part D plans, we also request that CMS clarify that the therapeutic alternatives considered in the Medicare Drug Price Negotiation Program are distinct from the therapeutic alternatives that Part D plans must identify for purposes of formulary submissions and the overall administration of the prescription drug benefit. This will help ensure that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs. CMS can do this via an HPMS memo to Part D plans...III. Part D plans may continue to identify therapeutic alternatives in enrollee communications consistent with existing practices, regardless of CMS's identification of therapeutic alternatives for Medicare Drug Price Negotiation Program. ..Apart from formulary development, the issue of a drug's therapeutic alternatives also has implications on communications Part D sponsors are required to provide to enrollees. The Annual Notice of Change (ANOC) describes any changes to the plan's benefits, formularies, and costs for the upcoming year. The Evidence of Coverage (EOC) document describes the plan's benefits, coverage, and exclusions. Real-time benefit tools (RTBT) provide prescribers with information at the point-of-care on formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). The monthly Explanation of Benefits (EOB) must include lower cost alternatives. ..While Part D plans are not required to include information about therapeutic alternatives in the ANOC or EOC, many voluntarily do so to help enrollees make informed decisions about their prescription drug coverage. This information is especially valuable for enrollees and prospective enrollees to fully understand the different treatment options available to them based on their unique circumstances. This transparency also promotes competition among Part D plans, as enrollees can better assess which plans are best for them. ..The RTBT and EOB rules have granted plans latitude in selecting which therapeutic alternatives would be displayed. CMS has stated that the "purpose of the beneficiary RTBT is to better inform beneficiaries about alternative medications," and thus, CMS allows "part D sponsors flexibility in implementing this requirement." For the EOB, CMS requires Part D sponsors to include lower-cost therapeutic alternatives but does not impose any specific requirements on plans on how they should identify those therapeutic alternatives...In summary, while Part D plans are required to communicate certain information to enrollees about therapeutic alternatives, CMS

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Question	Sub-Question	Response
	<p data-bbox="262 435 609 678">Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28 Evidence Submitted include a cost-effectiveness measure?</p> <p data-bbox="262 719 609 784">What type of Evidence is shown?</p>	<p data-bbox="609 251 1967 427">provides plans with significant flexibility in the selection of those therapeutic alternatives. As such, CMS should explicitly clarify that the information on therapeutic alternatives that Part D plans choose to communicate to enrollees in required enrollee communications to beneficiaries and other regulatory requirements is not affected by CMS's selection of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program.</p>
<p data-bbox="63 1109 262 1279">Question 29: Comparative Effectiveness on Specific Populations</p>	<p data-bbox="262 849 609 881">Response to Question 29</p> <p data-bbox="262 954 609 1052">Hyperlink to Citation - Additional Materials for Question 29</p> <p data-bbox="262 1166 609 1295">Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29</p> <p data-bbox="262 1352 609 1450">Evidence Submitted include a cost-effectiveness measure?</p> <p data-bbox="262 1482 609 1547">What type of Evidence is shown?</p>	

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Question	Sub-Question	Response
Question 30: Addressing Unmet Medical Needs	Response to Question 30 Hyperlink to Citation - Additional Materials for Question 30 Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30 Evidence Submitted include a cost-effectiveness measure? What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	

Answers to Question #28 for Public Submission

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments regarding the therapeutic alternatives for Sitagliptin. Our members help administer the Part D prescription drug benefit on behalf of many Part D plan sponsors, and a central component of that function is the identification of therapeutic alternatives to develop comprehensive prescription drug formularies consistent with applicable statutory, regulatory, and clinical requirements, including ensuring formularies are not discriminatory.

In general, while we understand that CMS cannot disclose the specifics of their negotiations with manufacturers of selected drugs, we believe the public is best served by CMS disclosing as much about this process as possible, and otherwise aligning its methodology for selecting therapeutic alternatives with how Part D plans select therapeutic alternatives. Our comments focus on emphasizing the differences between identifying therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program, and the role that the identification of therapeutic alternatives plays under the Medicare Part D program's formulary standards and enrollee communication requirements. PCMA has three main points:

1. As a general principle, CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for the Part D program.
2. CMS should clarify in an HPMS memo to Part D plans that CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program will not impact the agency's existing approach towards evaluating Part D formulary design for compliance with Part D formulary requirements.
3. CMS should clarify in an HPMS memo that Part D plans retain discretion on how to communicate therapeutic alternatives to enrollees, and that CMS's identification of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program will not affect these enrollee communications.

We discuss these issues in more detail below.

I. CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for their formulary submissions.

Currently, Part D plan sponsors consider a variety of factors when identifying therapeutic alternatives for their formulary submissions, including but not limited to (i) clinical effectiveness, (ii) safety, (iii) price, (iv) availability, and (v) patient preferences. Importantly, these factors are considered within a regulatory framework that imposes certain overarching formulary requirements.

First, Part D plans must ensure that their formulary designs are nondiscriminatory.¹ CMS considers several criteria when assessing whether a formulary is nondiscriminatory. CMS may presumptively approve formulary designs which align with the United States Pharmacopoeia's (USP) Medicare Model Guidelines (MMGs) based on the view that the MMGs reflect a

¹ See 42 C.F.R. § 423.272(b)(2).

scientifically and-clinically-based taxonomy developed by an independent expert body without a vested financial interest in the Part D program. The MMGs are also important because they provide a guiding framework for Part D plans to use when determining therapeutic alternatives. The MMGs group drugs into categories and classes. These categories and classes generally encompass the universe of potential therapeutic alternatives for a given medical condition. This means that Part D plans can use the MMGs to identify the range of therapeutic alternatives to consider when developing their formularies.

Second, Part D plans must provide an adequate formulary, which among other things, means including at least two Part D drugs within a particular category or class of Part D drugs.² This minimum formulary standard helps ensure a wide range of treatment options for enrollees, even if they have complex or rare medical conditions. Additionally, this requirement promotes patient choice and competition among drug manufacturers because the ability for patients to access alternative treatments incentivizes drug manufacturers to lower prices and innovate. The requirement to include at least two drugs per category or class helps to ensure that patients with a given medical condition have at least two formulary treatment options available to them, even if there are few therapeutic alternatives. This requirement is important because it prevents Part D plans from excluding entire categories or classes of drugs from their formularies.

Third, Part D plans must consider cost sharing in the development of formularies. For example, CMS could raise concerns about formularies that place drugs on high cost-sharing tiers without placing therapeutic alternatives in preferable positions.³ CMS has also expressed concerns about "adverse tiering" where a plan sponsor assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high-cost medical condition to a high cost-sharing tier.⁴ In short, Part D plans must consider the enrollee's share of costs for a particular drug when considering therapeutic alternatives.

PCMA encourages CMS to identify therapeutic alternatives for the Medicare Drug Price Negotiation Program in the same way that Part D plans do for their formularies. This would ensure consistency in process across two closely related programs and avoid introducing multiple, confusing standards for the same underlying definitional term. At the very least, aligning the selection of therapeutic alternatives under the Medicare Drug Price Negotiation Program with Part D formulary submissions would give Part D plans some assurance that CMS's assessment of their formulary submissions will not be affected by CMS's own process of selecting therapeutic alternatives.

II. CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program should not compromise the agency's evaluation of the adequacy of Part D plan formulary design, ensuring that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs.

PCMA acknowledges that CMS's identification of therapeutic alternatives under the Medicare Drug Price Negotiation Program is required by law and essential for successful drug pricing

² *Id.* at §

³ § 30.2.7, Chapter 6, Medicare Prescription Drug Manual ("The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.").

⁴ 87 Fed. Reg. 27208, 27303 (May 6, 2022).

negotiations. As stated above, we urge CMS to attempt to align its selection of therapeutic alternatives with how Part D plans select therapeutic alternatives.

That being said, it is important to recognize that the exercise of selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program and the Part D program, while overlapping in some areas, are ultimately distinct. Selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program requires unique considerations that are not fully applicable to how Part D plans identify and leverage therapeutic alternatives for formulary development.⁵ Accordingly, we do not expect CMS to perfectly align itself with Part D plan sponsor methodologies for selecting therapeutic alternatives.

First, therapeutic alternatives are a statutory feature of the Medicare Drug Price Negotiation Program. CMS selects therapeutic alternatives when negotiating pricing for selected drugs because the statute *requires* the agency to do so. Even if the statute did not require CMS to identify therapeutic alternatives, CMS would likely need to do so because it supports the agency in carrying out its statutory mandate to negotiate a "maximum fair price" (MFP) with manufacturers. Importantly, the MFP applies in a vacuum without regards to affordability and relative competitiveness with other drugs that a beneficiary may access.

By contrast, while Part D plans are required to select therapeutic alternatives for formulary submissions, Part D plans select therapeutic alternatives based on a delicate balance between clinical comparability, cost-effectiveness, and beneficiary access. Unlike CMS, which is required to focus on a single drug in isolation when assessing therapeutic alternatives, Part D plans, PBMs, and their pharmacy and therapeutics (P&T) committees are tasked with developing comprehensive formularies that holistically meet the complex needs of their enrollees. Part D plans must, already, cover selected drugs on their formularies under the statute,⁶ and CMS's interpretation worryingly suggests that such coverage may also involve a preferred status designation.⁷ Additional indirect restrictions on formulary design stemming from CMS's evaluation criteria under the Medicare Drug Price Negotiation Program could significantly hamper Part D plans' ability to offer competitive plan designs. In light of the comprehensive considerations that Part D plans must consider in developing formularies, CMS must ensure plans retain flexibility to adequately weigh all of these factors when developing formularies, including identifying therapeutic alternatives.

Second, CMS's selection of therapeutic alternatives is a one-time event, done solely to determine the MFP for a selected drug. Once the MFP is determined, the drug's therapeutic alternatives play no further role in how Medicare beneficiaries access the selected drug.

In contrast, a Part D plan sponsor's selection of therapeutic alternatives is used in multiple ways, including formulary design, coverage determination, tiering exceptions, and Part D appeals. This means that Part D plans must carefully consider all potential scenarios in which their selection of therapeutic alternatives may be challenged.

Third, CMS's identification of therapeutic alternatives for purposes of the Drug Price Negotiation Program is nonpublic. CMS indicates in the Revised Guidance for the Medicare Drug Price

⁵ See 42 C.F.R. § 423.128(d)(4)(ii).

⁶ Social Security Act § 1860D-4(b)(3)(I).

⁷ See § 110, Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023), <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

Negotiation Program that the agency will not unilaterally disclose any information pertaining to its negotiations with manufacturers, including the therapeutic alternatives identified for such negotiations. As a result, Part D plans do not have access to the therapeutic alternatives that CMS identifies for selected drugs. It would be unfair and arbitrary for CMS to evaluate Part D plan formulary submissions, including the identification of therapeutic alternatives contained in the submission, on a criteria that CMS never releases to the public. Formulary guidelines like the USP Medicare Model Guidelines provide a more predictable basis for administering a prescription drug benefit than nonpublic information.

In short, while we urge CMS to align its methodology for selecting therapeutic alternatives as much as possible with Part D plans, we also request that CMS clarify that the therapeutic alternatives considered in the Medicare Drug Price Negotiation Program are distinct from the therapeutic alternatives that Part D plans must identify for purposes of formulary submissions and the overall administration of the prescription drug benefit. This will help ensure that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs. CMS can do this via an HPMS memo to Part D plans.

III. Part D plans may continue to identify therapeutic alternatives in enrollee communications consistent with existing practices, regardless of CMS's identification of therapeutic alternatives for Medicare Drug Price Negotiation Program.

Apart from formulary development, the issue of a drug's therapeutic alternatives also has implications on communications Part D sponsors are required to provide to enrollees. The Annual Notice of Change (ANOC) describes any changes to the plan's benefits, formularies, and costs for the upcoming year. The Evidence of Coverage (EOC) document describes the plan's benefits, coverage, and exclusions. Real-time benefit tools (RTBT) provide prescribers with information at the point-of-care on formulary and benefit information (including cost, formulary alternatives, and utilization management requirements).⁸ The monthly Explanation of Benefits (EOB) must include lower cost alternatives.⁹

While Part D plans are not required to include information about therapeutic alternatives in the ANOC or EOC, many voluntarily do so to help enrollees make informed decisions about their prescription drug coverage. This information is especially valuable for enrollees and prospective enrollees to fully understand the different treatment options available to them based on their unique circumstances. This transparency also promotes competition among Part D plans, as enrollees can better assess which plans are best for them.

The RTBT and EOB rules have granted plans latitude in selecting which therapeutic alternatives would be displayed. CMS has stated that the "purpose of the beneficiary RTBT is to better inform beneficiaries about alternative medications," and thus, CMS allows "part D sponsors flexibility in implementing this requirement."¹⁰ For the EOB, CMS requires Part D sponsors to include lower-cost therapeutic alternatives but does not impose any specific requirements on plans on how they should identify those therapeutic alternatives.

⁸ § 119, Title I, Division CC, Consolidated Appropriations Act, 2021, Pub. L. No. 117-328 (amending section 1860D-4); *see also* 86 Fed. Reg. 5864, 5868 (Jan. 19, 2021).

⁹ 42 C.F.R. 423.138(e)(5).

¹⁰ 86 Fed. Reg. 5864, (May 6, 2022).

In summary, while Part D plans are required to communicate certain information to enrollees about therapeutic alternatives, CMS provides plans with significant flexibility in the selection of those therapeutic alternatives. As such, CMS should explicitly clarify that the information on therapeutic alternatives that Part D plans choose to communicate to enrollees in required enrollee communications to beneficiaries and other regulatory requirements is not affected by CMS's selection of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program.