Evaluation of the Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO): Final Report

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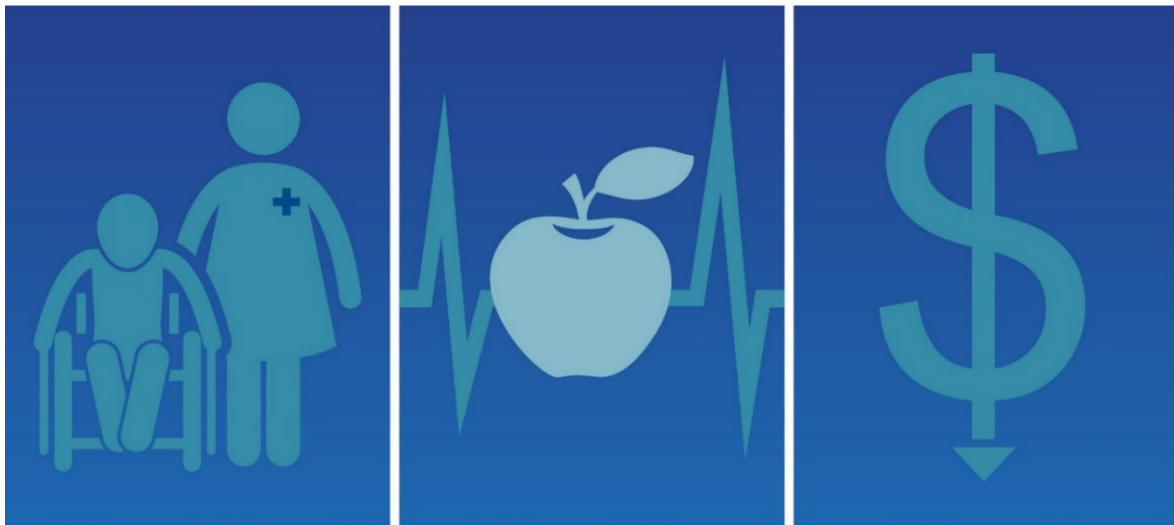
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Better Care, Healthier People, Smarter Spending

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Overview

In 2015, the Centers for Medicare & Medicaid Services (CMS) launched a three-year prior authorization model for hyperbaric oxygen (HBO) therapy in selected states that were found to have high improper payment rates[1] compared to other states. Prior authorization is a utilization management strategy intended to reduce improper payments by requiring claims for services to be reviewed by a health care payer for compliance with coding, billing, and coverage rules (including medical necessity) before services are rendered to beneficiaries and claims are submitted for payment. Thus, prior authorization promotes both general cost containment and control of waste, fraud, and abuse.

The purpose of the model was to test whether prior authorization could lower Medicare expenditures by reducing the provision of non-covered outpatient HBO therapy without adversely affecting access to or quality of care for beneficiaries. Non-emergent HBO provides a therapeutic dose of oxygen by exposing a patient's entire body to pure oxygen under increased atmospheric pressure. The resulting higher oxygen concentration in the bloodstream has the potential to improve wound healing—for example, for wounds from diabetic neuropathy or for soft tissue damage from radiation treatment. HBO therapy is a covered service under Medicare Part B if the receiving beneficiary meets specified criteria. However, past audits of Medicare claims and medical records revealed a high improper payment rate for HBO therapy.

Implementation of the model began in April 2015 in Michigan, followed by Illinois and New Jersey in August 2015.[2] The model concluded in February 2018.

The evaluation

CMS contracted with Mathematica Policy Research to conduct an evaluation of the prior authorization model for non-emergent HBO therapy in Illinois, Michigan, and New Jersey. The goal of the evaluation was to rigorously assess prior authorization as a means of reducing payments for medically unnecessary services, thereby reducing costs and improper payments while maintaining or improving the quality of care provided to beneficiaries. In this report, which addresses 10 quarters of model experience, we provide findings from our final evaluation of the HBO prior authorization model. The approach taken in this report is similar in methodology and focus to our earlier interim report.[3] The reader should refer to this prior report for additional background and a more in-depth discussion of methods.

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[1] These improper payment estimates were determined through CMS' Comprehensive Error Rate Testing (CERT) program.

[2] The model ended on February 28, 2018. There are no current plans for it to be extended or expanded.

[3] A prior evaluation report examining six quarters of model experience (Interim Report for the Evaluation of Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO)) is available at https://innovation.cms.gov/files/reports/interimevalrpt-mpa-hbo.pdf.

We organized the guiding research questions for the evaluation around four domains:

1. **Utilization and expenditures.** How does the HBO prior authorization model affect Medicare service utilization and expenditures? Does the model realize savings on fee-for-service (FFS) expenditures for the Medicare program?

2. **Quality of care.** How does the HBO prior authorization model affect the quality of care for Medicare beneficiaries? Are there any adverse outcomes associated with the model?

3. **Claim denials.** Does HBO prior authorization affect the rate of claim denials?

4. **Model operations.** How was the HBO prior authorization model operationalized by the Medicare Administrative Contractors (MACs)? Were opportunities for improvement identified?

The evaluation used a mixed-methods approach that combined quantitative and qualitative data analysis to (1) measure overall service utilization, cost, and quality impacts and (2) understand the model's implementation experience. The quantitative analysis design included beneficiaries in the model or comparison group states with any of five applicable conditions.[4] These five included conditions are a subset of a larger group of conditions that qualify beneficiaries for HBO and were distinguished by a requirement that HBO would be provided only following or in conjunction with standard therapy. The most common of these is lower extremity wounds associated with diabetes.[5] This condition represents 80% of the analysis sample.

The evaluation examined the experience of beneficiaries with any of these five conditions from the time they received a relevant diagnosis. Beneficiaries remained in the model until death, a move out of their (model or comparison) state of residence, or until they no longer have Part A and B Medicare FFS enrollment. Our approach enabled us to examine long-term outcomes that may be affected by treatment of their qualifying conditions.

The quantitative analysis used both descriptive and multivariate analysis methods, specifically difference-in-differences (DID), to estimate the model's impact. For this report, we analyzed quarterly utilization and expenditure data on beneficiaries from April 2012 through December 2017. We estimated model effects by comparing 1) the change over time in key outcomes between the pre-model (April 2012 to April 2015) and model (April 2015 to December 2017) periods in the three model states and 2) the change over the same time for beneficiaries with the same diagnoses in non-model states that shared a MAC with the model states. We established balance between the model and comparison states on the mix of qualifying health conditions and important demographic characteristics. In our regression analyses, we controlled for qualifying health condition and for Hierarchical Condition Category (HCC) score, a proxy for overall health, to account for remaining differences in clinical condition between model and control beneficiaries. Information on how comparison states were selected is found in Appendix A.

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[4] Chapter I, Table I.1 provides information on the conditions that were subject to prior authorization.

[5] To qualify for HBO, a wound must be Wagner stage III or higher. Wound stage information is not included in claims data, so we include all lower extremity wounds in our study.

The goal of the qualitative analysis was to understand implementation of the model. The qualitative analysis relied on structured interviews with the MAC personnel responsible for administering the HBO model in Illinois, Michigan, and New Jersey under contract to CMS. We conducted interviews with MAC personnel in spring 2018, shortly after the prior authorization model ended, to understand more fully the experience of implementing the model on Medicare program operations.[6]

Findings

Our findings on the effects of prior authorization for HBO services suggest that the model was effective in reducing HBO utilization by around 15 percent and cost by approximately 35 percent ($59 per beneficiary per quarter). However, we did not find that total Medicare expenditures decreased in model states relative to the comparison states. Indeed, we estimated an increase in total Medicare expenditures in one state (Illinois).

Our estimates provided no evidence that the model reduced quality of care or increased adverse events in the full study population. We found no evidence of an increase in emergency department (ED) utilization, unplanned hospitalization, or mortality.

As part of our analysis, we examined quality and adverse events within the subpopulation of patients with diabetic lower extremity wounds. Impacts were generally small and not statistically significant. Four of the five measures showed no statistically significant impact.[7] We found a small (0.03 percentage point) increase in the rate of emergency department utilization for lower extremity wounds among beneficiaries with diabetic lower extremity wounds from a baseline rate of 0.5 percent. In addition, we found a small (0.2 percentage point) increase in the rate of amputations among beneficiaries with diabetic lower extremity wounds in Michigan from a baseline rate of 2.6 percent. These are small changes in relatively rare outcomes, and are unlikely to reflect large issues with access to and quality of care.

MAC staff reported that the prior authorization model was implemented with few difficulties. They felt the model achieved its goals of reduced non-medically necessary HBO service utilization and savings for the Medicare program. Some MACs continued to use generic procedures and guidelines from the model after it ended, including processes, systems, and tools such as checklists.

MAC staff did identify changes that they believed could have been made to make the model easier for them to implement and less burdensome for providers. As in the interim report, the MACs reported that providers questioned the clinical experience of reviewers and expressed concerns about inconsistencies in the reviews. They also said that stakeholders (the MACs and providers) had different interpretations of the coverage guidelines due to disparate outreach and

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[6] The qualitative analyses performed in this evaluation includes additional sources. A discussion of results based on interviews with HBO providers and patients were discussed in the first interim report (Interim Report for the Evaluation of Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO)) is available at https://innovation.cms.gov/files/reports/interimevalrpt-mpa-hbo.pdf.

[7] We found a statistically significant increase of 0.03 percentage points (5.7 percent) in the probability of an emergency department visit for treatment of a lower extremity wound. We found no statistically significant impacts on the number of emergency department visits for lower extremity wounds, the probability or number of unplanned hospitalizations for lower extremity wounds, or amputation.

education, as well as differences in interpretation. A new concern presented by MAC staff in follow-up interviews was difficulty early in model implementation with system integrations, which required manual reporting and matching of claims by MACs until the integration was complete.

Table ES.1 presents findings based on quantitative and qualitative data from model states for the evaluation's core questions. The body of the report discusses these findings along with the supporting data and analyses.

Table ES.1. HBO evaluation findings

Utilization and expenditures
Prior authorization reduced HBO service use and Medicare expenditures.

- We estimated decreases in the probability of HBO utilization (16 percent) and the number of HBO treatments (25 percent) for beneficiaries with diabetic lower extremity wounds. These similarly decreased among beneficiaries with any of the five included conditions.
- HBO expenditures decreased by over 30 percent relative to the comparison group for both the full target population and for beneficiaries with diabetic lower extremity wounds.
- The decrease in HBO service use did not translate into savings in total Medicare expenditures for the study population.
- These findings are consistent for rural/urban and dual-eligible/Medicare-only subgroups.

Quality of care
Prior authorization did not appear to reduce the quality of care or increase adverse events overall.

- Prior authorization did not appear to either reduce the quality of care received by beneficiaries or increase adverse events overall, as measured by emergency department utilization, unplanned hospitalization, or mortality.
- Among beneficiaries with diabetic lower extremity wounds, we found a small increase in emergency department use for lower extremity wounds and a small increase in amputation rates in Michigan.

Denied claims
Denied claims initially rose but later reverted to their pre-model level.

- In the first two quarters after implementation, we observed an increase in the proportion of denied claims, but the claim denial rate appeared to revert to the pre-model rate by the third quarter after implementation. This pattern may reflect a learning period during which HBO providers became accustomed to the more strictly enforced pre-existing documentation requirements.

MAC operations
The MACs reported few challenges.

- In interviews, MAC staff reported efficient and effective model implementation with few challenges. MAC staff identified changes that they believed could have been made to make the model easier for them to implement and less burdensome for providers. These changes included:
    - Requiring HBO providers to complete test submissions prior to the model's start to uncover potential system issues as well as to help providers better understand the prior authorization guidelines
    - Providing increased HBO provider and staff education during pre-implementation or the early stages of the model
    - Promoting consistency in reviews through internal quality assurance both within and between MACs
    - Updating the NCD to make coverage guidelines more current and explicit for all providers
- MAC staff reported that providers' perceived delays in obtaining final PAR determinations became less of an issue over time as providers became more familiar with document requirements enforced under the model.
- Overall, MAC staff follow-up interviews support the findings from previous MAC interviews discussed in the interim report[8].

HBO = hyperbaric oxygen; MAC = Medicare Administrative Contractor, NCD = National Coverage Determination.

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[8] A prior evaluation report examining six quarters of model experience (Interim Report for the Evaluation of Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO)) is available at https://innovation.cms.gov/files/reports/interimevalrpt-mpa-hbo.pdf.

Limitations

The primary limitation of our analysis concerns the use of claims data to identify likely HBO candidates and assess the quality of their care. From available claims data, we could not assess condition severity or rate of healing, and could, therefore, not observe the characteristics that MACs used to judge whether HBO treatment was covered for a given beneficiary. We relied on claims indicating the presence of one of the conditions covered by the prior authorization model, and therefore our study population likely contains beneficiaries whose condition is not (or is not yet) severe enough to warrant HBO. The large variation in total Medicare expenditures, partly due to broad inclusion criteria, may make it difficult to identify any changes in total expenditures attributable to the model. Likewise, our risk-adjustment strategy involved controlling for diagnosis group and for HCC scores based on diagnosis codes in claims data, which may not account for all relevant clinical factors that might influence the impact of the model. Also, geographic variation in coding practices might therefore have decreased our ability to control for general health risks.

A limitation of the qualitative analysis is that it is possible that the views of the staff we interviewed from each of the three MACs that implemented the model was not representative of the experiences and perceptions of all MAC staff. We did select several staff to interview from each MAC and generally found responses by staff within a MAC to be consistent. That said, we cannot be certain that other staff would share the selected staff's perceptions.

A further potential limitation is that we used a quasi-experimental design. The gold standard for evaluations—random assignment—was not possible for this study because CMS selected states based on pre-model utilization levels. Any quasi-experimental design such as this one could yield distorted impacts if the comparison group observations were subject to different unobserved changes than the model group observations. Spillover effects from the model to the comparison states could also contaminate our evaluation design. However, our analyses suggested that such concerns were minor for this analysis. Our efforts to select a credible comparison group from neighboring states serviced by the same MACs as the model states—by weighting to make the selected comparisons closely match our model states—and our DID regression models likely removed major sources of bias in our main estimates.

I. INTRODUCTION

Non-emergent hyperbaric oxygen (HBO) therapy provides a therapeutic dose of oxygen by exposing a patient's entire body to pure oxygen under increased atmospheric pressure. The resulting higher oxygen concentration in the bloodstream improves wound healing—for example, for non-healing wounds related to advanced diabetes or for soft tissue damage from radiation treatment. HBO therapy takes place in a pressurized, atmosphere-controlled chamber, and typically lasts 90 to 120 minutes per treatment. Depending upon the condition being treated, HBO therapy is usually administered in one to two sessions per day, five days per week. In our study population, the average number of HBO therapy sessions received by an HBO user was around 30-35, depending on the qualifying condition. The mean payment amount per individual session in 2012 for the beneficiaries in our analysis was $339.44.

Medicare covers HBO therapy as treatment for a limited set of conditions. However, past audits of Medicare claims and medical records have revealed a high improper payment rate for HBO therapy. A 2000 report by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that more than 38 percent of the Medicare payments to outpatient facilities and physicians for HBO therapy in the audit sample were for inappropriate or excessive treatment (HHS 2000). The OIG also raised concerns about quality of care in HBO treatment, citing a lack of physician monitoring during treatment or appropriate testing to confirm diagnoses that supported the use of HBO.

Typically, HBO claims, like Medicare claims in general, are processed by Medicare Administrative Contractors (MACs) operating at a regional level. MACs may review a certain portion of claims for medical necessity as a form of quality control. In 2006, Medicare first issued a National Coverage Determination (NCD) for HBO therapy that listed 15 clinical conditions for which HBO therapy could be considered medically necessary (either alone or as an adjunctive therapy), as well as clinical conditions for which HBO therapy was not deemed to be medically necessary and therefore not covered by Medicare (Centers for Medicare & Medicaid Services [CMS] 2006).[9,10] Since the first NCD in 2006 there have been no changes to the list of clinical conditions for which HBO therapy could be considered medically necessary, including the most recent NCD revision in 2017.

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[9] The NCD (CMS 2006) also includes specific guidelines regarding the use of HBO therapy to treat diabetic lower extremity wounds, which is a key focal population of our analysis: "The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment."

[10] Some states (including New Jersey) have Medicare Administrative Contractor jurisdictions that operate under local coverage determinations that they develop and may be stricter than the NCDs set forth by Medicare.

To test if prior authorization could improve compliance with Medicare coverage rules, CMS launched a model in which HBO treatment in certain states and for certain clinical conditions was subject to prior authorization. This report summarizes findings from an impact evaluation of that model.

A. Model background

Prior authorization is a utilization management strategy intended to reduce improper payments by requiring that the health care payer review claims for services to assess compliance with coding, billing, and coverage rules (including medical necessity) before providers render services to beneficiaries and submit claims for payment. Thus, prior authorization is designed to contain costs and reduce waste, fraud, and abuse. Several other government and private sector health care payers already use prior authorization practices (TRICARE 2016; American Medical Association 2013), including Medicare Part D pharmaceutical plans (HHS 2015). Research indicates that such approaches can be effective in reducing expenditures on the service or benefit covered by the prior authorization requirement (MacKinnon and Kumar 2001; Asher et al. February 2018). A CMS model involving prior authorization for power mobility devices has shown a large decrease in monthly expenditures on included devices (CMS 2014). In addition, the evaluation of prior authorization for repetitive scheduled non-emergent ambulance transport (RSNAT), which was conducted under this evaluation contract, also demonstrated large decreases in expenditures and utilization for RSNAT services (Asher et al. February 2018). By ensuring that a service is covered before a claim is paid, prior authorization may lower Medicare fee-for-service (FFS) spending while maintaining or improving quality of care. However, there is a risk that some beneficiaries may experience denial or delay of needed care because of prior authorization requirements (Bergeson et al. 2013).

In April 2015, the prior authorization model for outpatient HBO therapy began in Michigan, followed by Illinois and New Jersey in August 2015. Approximately 113 HBO providers across these three states were affected. CMS selected the states based on high rates of HBO utilization and claims error rates. The model continued through February 2018.

There are 15 conditions covered for HBO use by Medicare Part B. Of these, five were deemed appropriate for the prior authorization model. In general, these conditions are non-urgent, involving wounds attributable to or worsened by advanced diabetes, infection, or tissue damage from cancer treatment. For these conditions, HBO should follow a course of prior treatment. Included conditions are presented in table I.1.

Under the RSNAT model, Part B providers intending to provide HBO services for one of these conditions were requested to submit relevant documentation prior to the start of treatment. The MAC would review the submitted material and assess whether medical necessity according to Medicare coverage rules had been demonstrated. Providers could resubmit and refine their documentation an unlimited number of times. Providers who failed to seek prior authorization for submitted outpatient HBO therapy claims were subject to prepayment review—a process usually reserved for a small portion of claims that stand out to reviewers because of beneficiaries' previous history or other factors. Prepayment review was included to ensure that providers in a model state who chose not to request prior authorization were not able to evade review of their HBO claims for medical necessity and appropriate use.

Submitted documentation was evaluated by trained MAC staff for compliance with coverage rules that are specified in either a National or a Local Coverage Determination (NCD or LCD) rule. The NCD/LCD states which conditions are covered and what course(s) of conventional therapy must be attempted prior to HBO. While Illinois and Michigan operated under the NCD set by Medicare, the MAC administering New Jersey had adopted an LCD for HBO that was more specific and in some ways stricter than the NCD. For example, the NCD did not specify a test or test result that indicated suitability for HBO; the LCD in effect in New Jersey specified that in most cases a beneficiary should have an ankle brachial index of no less than 0.6.

An affirmative prior authorization decision permitted up to 40 courses of treatment during a 12-month time period. Beneficiaries who exceeded 40 courses of treatment in 12 months required an additional prior authorization request (PAR).

Table I.1. Conditions included in the HBO prior authorization model

Condition	Medical necessity guidelines	MAC-guidance on documentation expectations (National)
Chronic refractory osteomyelitis, an infection in a bone	HBO therapy is covered only when the condition is unresponsive to conventional medical and surgical management.	Medical records should: • Support an initial diagnosis of osteomyelitis with a report of a diagnostic procedure, such as (but not limited to) computed tomography (CT), magnetic resonance imaging (MRI), or bone scan. • Identify the conventional medical management to which the patient did not respond. • Identify the conventional surgical management to which the patient did not respond. • Support that the diagnosis of chronic refractory osteomyelitis has been unresponsive to both medical and surgical management.
Osteoradionecrosis, a complication of radiation therapy involving bone death	HBO therapy is covered only as an adjunct to conventional therapy.	Medical records should: • Identify the anatomical location, the reason, and the dates the radiation treatment was received. • Support the diagnosis of osteoradionecrosis with a report of a diagnostic procedure, such as (but not limited to) X-ray, CT, or MRI. • Identify the conventional treatment or therapy the patient is receiving.
Soft tissue radionecrosis, a complication of radiation therapy involving soft tissue death	HBO therapy is covered only as an adjunct to conventional therapy.	Medical records should: • Identify the anatomical location, the reason, and the dates the radiation treatment was received. • Support the diagnosis of soft tissue radionecrosis with a report of a diagnostic procedure, such as (but not limited to) visual examination, biopsy, or CT. • Identify the conventional treatment or therapy the patient is receiving.

Condition	Medical necessity guidelines	MAC-guidance on documentation expectations (National)
Actinomycosis, a chronic, slow-growing infectious bacterial disease	HBO therapy is covered only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment.	Medical records should: • Identify the location of the infection. • Support the diagnosis of actinomycosis with a report of a diagnostic procedure, such as (but not limited to) results of sputum, pus, or biopsy specimen cultures. • Support the surgical incision and drainage of lesions. • Identify the prolonged administration of appropriate antibiotics. • Identify the conventional treatment or therapy the patient is receiving.
Diabetic wounds of the lower extremities	HBO therapy is covered only if (1) the patient has type 1 or type 2 diabetes and a lower extremity wound due to diabetes; (2) the patient has a wound classified as Wagner Grade III or higher;[a] and (3) the patient has failed an adequate course of wound therapy, as defined in the NCD.	Medical records should: • Include an assessment of patient's vascular status and correction of vascular problems if possible, such as (but not limited to) ankle-brachial index, toe signals, or interventions performed by a vascular surgeon. • Support optimization of nutritional status, such as (but not limited to) lab work and dietetic teaching. • Support optimization of glucose control, such as (but not limited to) hemoglobin A1c or serial glucose levels. • Describe debridement to remove devitalized tissue. • Identify wound care management that includes maintenance of a clean, moist bed of granulated tissue with appropriate moist dressing. • Identify appropriate off-loading. • Identify treatment to resolve any infections.

[a]We relied on the set of diagnosis codes listed as indicating a covered condition by the LCD issued by Novitas Solutions (the MAC for New Jersey). To the extent these diagnosis codes encompass a broad range of conditions, we may include beneficiaries for whom HBO is not (or not yet) a covered treatment.

Source: CMS, National Government Services, Novitas Solutions, and Mathematica interviews with MAC and industry physicians.

HBO = hyperbaric oxygen; MAC = Medicare Administrative Contractor; NCD = National Coverage Determination.

B. Overview of the evaluation

This evaluation measured the impact of the prior authorization model on the Medicare program (including the MACs), as well as on Medicare beneficiaries. The evaluation had three primary objectives:

• Estimate the impact of prior authorization on the volume of HBO services delivered.

• Estimate the impact of prior authorization on expenditures associated with HBO treatments, as well as any impact on total Medicare expenditures in the relevant beneficiary groups.

- Assess whether enforcing existing coverage rules through prior authorization was associated with a change in beneficiaries' quality of care or adverse outcomes.

- Understand how the model was implemented from the perspective of key stakeholders and determine whether there are lessons to be learned to improve future compliance efforts.

1. Data sources and outcome measures

Mathematica employed a mixed-methods evaluation design comprising both quantitative data analysis and qualitative data collection to respond to CMS's research questions (see Table I.2). The quantitative analysis relied on Medicare claims data and addressed model impacts such as changes in claims volume and cost savings, along with impacts perceived on the ground by the MACs that administered the model.

We conducted both descriptive and multivariate analyses of key quantitative indicators for the model and comparison group states. Our analysis was performed at the beneficiary level using model and comparison groups we constructed. We examined intended outcomes, such as changes in the volume of HBO services and total HBO utilization and cost. We also examined unintended outcomes, including impacts on quality and adverse events, which were reflected in measures such as changes in unplanned hospitalizations, amputations, and deaths.

In addition to the quantitative analysis, we conducted a qualitative analysis that consisted of telephone interviews with personnel from the three MACs servicing model states and a review of PARs. These conversations followed up on the perceptions of MAC staff from the interim report about the implementation of the three-year prior authorization model on Medicare program operations. We also present summary findings from the interim report.

Table I.2. Evaluation research questions and data source

Research and analysis question	Quantitative analysis	Qualitative analysis
Utilization and expenditures		
How does the prior authorization model affect Medicare service use and cost? Was the model cost-effective for the Medicare program?		
How does prior authorization affect		
1. Total HBO therapy service use?	X	X
2. Total payments for HBO service?	X	
3. Total payments for HBO and wound therapy service?	X	
4. Total Medicare expenditures?	X	
How did medically unnecessary HBO therapy use change?		X
Quality of care and adverse outcomes		
How does the prior authorization model affect the quality of care and likelihood of adverse outcomes?		
Does prior authorization affect		
1. Unplanned inpatient hospitalizations?	X	
2. Emergency department visits?	X	
3. Amputation of lower extremity?	X	
4. Death?	X	
Did beneficiaries experience a delay in services?		X

Research and analysis question	Quantitative analysis	Qualitative analysis
MAC Program operations		
How does the prior authorization model affect Medicare program operations?		
What was the impact of the model on MAC operations?		
1. How was prior authorization implemented by each MAC?		X
2. How were staff assigned to prior authorization activities selected, hired, and trained?		X
3. How long did it take prior authorization staff to process decisions?		X
4. How much of a time and cost burden does prior authorization present?		X
Providers		
How does the prior authorization model affect providers?		
What was the impact of the model on providers' operations? Did participants consciously change practices in response to the model and, if so, how?		
1. Were there changes in providers' Management practices? Care provision? Patient admission procedures? Communications? Case volumes? Medicare payments? Overall profitability? Fiscal solvency?		X
2. Have HBO providers received appropriate information from MACs and other sources for submitting PARs correctly?		X
3. Were patient services delayed because of approval delays?		X
4. Does prior authorization reduce HBO providers' uncertainty regarding claim approval?		X
5. Does prior authorization reduce providers' burden related to appealing denied claims?		X
Claims denials		
How does the prior authorization model affect error rates for payments or claims?		
Does prior authorization affect claims denial rates?	X	

II. QUANTITATIVE DATA ANALYSIS METHODS

Our quantitative analysis uses a difference in differences approach. We compare the change in outcomes in states affected by the model before and after the model went into effect to the change in outcomes for a set of comparison states over the same time period. The treatment group consists of individuals residing in Illinois, Michigan, and New Jersey whose medical claim record indicates the presence of one of the five included conditions. We compared their experience in the quarters following diagnosis to that of beneficiaries with the same diagnoses residing in other states.

A. Data and population

We used final action claims for Medicare FFS beneficiaries for dates of service from January 2012 through December 2017.[11] Prior authorization started in Michigan on April 13, 2015 (Quarter 14), and on August 1, 2015 (Quarter 15), in Illinois and New Jersey. Claims from Quarter 1 (January through March 2012) were used only to identify beneficiaries with the included condition—our analysis includes utilization and expenditures from April 2012 through December 2017.[12] Below we describe our comparison group, population restrictions, weighting strategy, and key analysis groups.

1. Comparison group

The comparison group consisted of beneficiaries residing in states in the same MAC jurisdictions as the model states (Figure II.1). Minnesota and Wisconsin are in the same MAC as Illinois (National Government Services); Indiana is in the same MAC as Michigan (Wisconsin Physician Services); and Delaware, Maryland, Pennsylvania, and Virginia are in the same MAC as New Jersey (Novitas Solutions). This approach was intended to capture an appropriate counterfactual policy and operational environment—that is, if the model states were not subject to the prior authorization model, claims from those states would be processed in the same way that claims from the comparison states were processed. In addition, because states in the same MAC jurisdiction were likely to be geographically adjacent, they may have shared regional characteristics that would affect health utilization, cost, and outcomes. More information on the comparison group selection is discussed in Appendix A.

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[11] We excluded duplicate and denied claims.

[12] We therefore have 11 or 12 pre-implementation quarters (depending upon the state) and 10 or 11 intervention quarters.

Figure II.1. Model states and their MAC jurisdictions
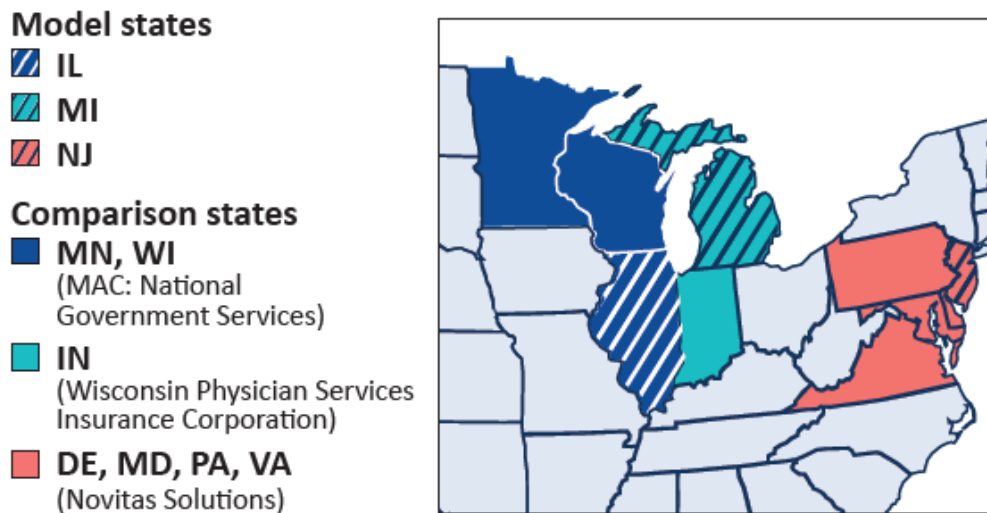
Our analysis assumed that there were no spillover effects across states within MAC jurisdictions, whereby beneficiaries in the comparison states could also be affected by the prior authorization model. Spillovers could occur if, for example, the MACs applied stricter scrutiny to HBO claims in non-model states due to increased vigilance of HBO claims submitted in model states. For the interim report, we conducted a number of additional analyses to test whether spillover effects of the prior authorization model were present, which could pose a threat to the validity of our estimates (Asher et al. June 2018). We found no evidence of spillovers specific to the included MACs and concluded that our comparison group strategy was appropriate.

2. Population restrictions

Our unit of analysis was person-quarter. We restricted our study population to beneficiaries who (1) were covered by Part B Medicare Fee for Service (FFS) in the given quarter; (2) were living in one of the included states (the model states—Illinois, Michigan, and New Jersey—or the comparison group of states that shared a MAC jurisdiction with one of these states); and (3) had a claim indicating a diagnosis[13] of one or more of the five conditions for which treatment with HBO was included in the prior authorization model.

We considered the effects of the model on beneficiaries following their first observed diagnosis of one or more of the following conditions:

- Chronic refractory osteomyelitis, an infection in a bone

- Osteoradionecrosis, a complication of radiation therapy involving bone death

- Soft tissue radionecrosis, a complication of radiation therapy involving soft tissue death

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[13] Because our claims data were truncated before January 2012, the diagnoses used for our inclusion criteria must have been received on or after January 1, 2012.

- Actinomycosis, a typically chronic, slow-growing infectious bacterial disease

- Diabetic lower extremity wounds

To ascribe a condition to a beneficiary, we required at least one inpatient claim or two outpatient claims that featured a relevant diagnosis code on different days no more than 90 days apart.[14] The diagnoses codes used to identify these five conditions were based on two sources. First, We obtained a set of ICD-9-CM and ICD-10-CM diagnosis codes identifying these conditions from Jurisdiction L's (Novitas Solutions) LCD used in New Jersey (CMS n.d.).[15] Second, we supplemented them with a small number of additional codes based on internal physician review. We considered those beneficiaries with a claim history indicating a covered condition to have had the condition from the date of the earliest claim in the qualifying set within the study period (which we referred to as the date of diagnosis). Once diagnosed, beneficiaries remained in our sample until they died, migrated out of their state of residence, or left FFS Medicare. Our total study population consisted of 109,336 model state beneficiaries (51 percent) and 104,883 comparison state beneficiaries (49 percent).[16] The length of time that we observed each beneficiary ranged from 1 to 24 quarters, with a mean duration of 8.2 quarters for model beneficiaries and 8.3 quarters for comparison beneficiaries, for a total of 1,766,258 beneficiary-quarters. More information on sample identification is in Appendix C.

We examined two beneficiary groups in this report. First, because beneficiaries with diabetic leg wounds comprised over 80 percent of the individuals in our sample, we conducted analyses focusing only on this group. Looking at a single condition allows for a greater degree of clinical coherence within the group and easier interpretation of some of the key outcomes.[17] Second, we examined the population of Medicare beneficiaries with any of the five conditions listed above, to study the impact of the model on the population of all affected beneficiaries.

Our design included beneficiaries from the date of their diagnosis and retained them in the sample to enable us to observe any long-term health outcomes affected by access to HBO therapy. The consequences of delayed or insufficient treatment of the included conditions may be short-term (such as delayed healing which can be difficult to assess using claims information) or long-term (such as amputation, in the case of diabetic lower extremity wounds, or higher rates of hospitalization or death). By keeping individuals in the study unless they died, moved, or left

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[14] Relaxing the requirement that the two diagnoses occur no more than 90 days apart did not appreciably change the results.

[15] To the extent these diagnosis codes encompass a broad range of conditions, we may have included beneficiaries for whom HBO is not (or not yet) a covered treatment. For example, diabetic lower extremity wounds are covered for treatment under the NCD if they are Wagner Grade III or higher, but the ICD-9 diagnosis coding system does not differentiate wound severity.

[16] We excluded 6,175 beneficiaries who moved between states during the study period.

[17] From available claims data, we do not have the information necessary to assess wound severity or rate of healing, and could therefore not observe the characteristics that MACs used to judge whether HBO treatment was covered for a given beneficiary. We used the set of diagnosis codes listed as indicating a covered condition by the LCD issued by Novitas Solutions (the MAC for New Jersey). To the extent these diagnosis codes encompass a broad range of condition severity, we may include beneficiaries for whom HBO therapy may not be a covered treatment.

FFS Medicare, we could observe these outcomes over time and assess whether the model increased the risk of adverse outcomes in the long run.[18]

3.   Weighting strategy

To develop the most effective comparison group possible and isolate the impact of the intervention, we sought to achieve balance between the model and comparison groups on observable characteristics such as demographics, diagnosis, and Medicaid enrollment. Our weighting approach involved calculating the predicted probability (propensity score) of being in the model group based on observable characteristics[19] and then constructing a set of inverse propensity score weights to balance out differences in those characteristics between the two groups of states.

The following characteristics were included in our predictive model:

(1) beneficiary age

(2) whether the person lived in a rural area (defined by metropolitan statistical area)

(3) gender

(4) race (separate indicators for black, white, Hispanic, or other)

(5) indicators for whether the beneficiary was diagnosed with osteomyelitis, osteoradionecrosis, soft tissue radionecrosis, actinomycosis, or diabetic ulcers of the lower extremities.

We balanced the characteristics of beneficiaries in the model and comparison states in each quarter, both within each MAC jurisdiction and across jurisdictions, to establish comparability for drawing inferences about the impact of the model. More information on this weighting strategy is presented in Appendix D.

B. Analytic approach

We used a combination of descriptive and multivariate analyses to address the research questions in Chapter I. We relied on SAS Enterprise Guide for data processing, with all regressions conducted in Stata 14.2.

1.   Descriptive analysis

We conducted descriptive analyses (that is, not adjusting for confounding factors) that illustrated high-level changes in utilization and expenditures. We considered the following

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[18] As a robustness check, we tested a model in which we included a set of indicator variables for the number of quarters since diagnosis. Our findings did not change.

[19] We estimated a logistic regression predicting treatment status for each eligible Medicare beneficiary living in a model or comparison state for each quarter of data, separately for each MAC jurisdiction.

utilization and expenditure measures for beneficiaries with a diabetic lower extremity wounds and for beneficiaries with any included condition:

- Quarterly probability of receiving HBO services

- Average quarterly payments to providers for HBO services

2. Multivariate analyses

Our multivariate difference-in-differences (DID) models enabled us to estimate the impact of the model by controlling statistically for observed confounding factors and netting out the changes in key outcomes in the comparison states over the study period. We examined utilization, expenditures, quality of care, and adverse outcomes at the beneficiary-quarter level.[20] We also estimated the model's effects on denied claims. For more information on outcome measure construction, please see Appendix C.

We generated weighted summary statistics of the demographic and health characteristics of beneficiaries in the model and comparison groups, as well as their baseline levels on the outcome measures. We also generated descriptive figures to illustrate the trends in HBO utilization and expenditures. See Appendix D for information on the beneficiary weights and Appendix C for methods used to create the figures.

We next used generalized DID to estimate the impact of prior authorization on each outcome. For binary variables, we used logistic regression. For count variables, we used negative binomial regression. For continuous variables, we used ordinary least squares (OLS). We controlled for demographic characteristics (age, sex, race, and rural residence), socioeconomic characteristics (dual eligibility for Medicare and Medicaid), and health characteristics (qualifying diagnosis and HCC score).[21] We weighted observations to improve balance on observable characteristics and adjusted standard errors to account for the effects of weighting and the non-independence of observations on the same individual in several quarters. We estimated impacts two ways. First, we estimated the overall effect of being in one of the three prior authorization states. Second, we estimated state-specific effects. More information on our regression methods, including robustness checks, can be found in Appendix C.

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[20] We dropped the first quarter of 2012 from our analyses to allow it to serve as a historical period for identifying conditions and non-HBO treatments.

[21] HCC scores are calculated using diagnosis codes. We could not control for relevant clinical characteristics such as wound severity that are not captured in claims data but may influence the effect estimates.

III. ESTIMATED IMPACTS OF HBO PRIOR AUTHORIZATION (QUANTITATIVE ANALYSIS RESULTS)

We present the results of our descriptive and multivariate analyses by research question domain. Within each domain, we first present the result from the focal group of individuals with diabetic lower extremity wounds, followed by results for the population of individuals with any condition that was included in the prior authorization model.

A. Descriptive information

1. Number of HBO providers

Over the study period, the number of HBO providers increased less in treatment states than in comparison states. The number of providers billing Medicare for HBO sessions for beneficiaries in the model and comparison states with the included conditions increased from 266 to 320 providers (Table III.1). The largest increases were in Pennsylvania, a comparison state, and New Jersey, a model state, although all states saw increases during the study period. However, the number of providers in model states increased by less than 1 percent (from 139 to 140 providers between 2014 and 2016), while the number of providers in comparison states increased by 8 percent (from 167 to 180 providers) during the same period. This contrasted with the growth rates during the pre-model period (2012 to 2014), which were similar for the two groups of states (17 percent for the model states versus 14 percent for the comparison states), suggesting that there may have been a deterrent effect on provider entry in the model states.

Table III.1. Number of providers billing Medicare for HBO sessions for beneficiaries with included conditions, 2012–2016 by state

Year	Model states				Comparison states							
	Illinois	Michigan	New Jersey	Model total	Delaware	District of Columbia	Indiana	Maryland	Minnesota	Pennsylvania	Wisconsin	Comparison total
2012	47	37	35	119	4	2	24	13	6	76	22	147
2013	49	39	43	131	4	2	28	13	7	78	23	155
2014	52	41	46	139	4	2	31	15	7	84	24	167
2015	53	46	48	147	4	3	29	17	7	86	26	172
2016	50	45	45	140	5	3	30	20	8	87	27	180

HBO = hyperbaric oxygen.

2. Beneficiary population

We divided the study population into diagnosis groups based on the first of the included diagnoses observed in their claims history.[22] The majority of beneficiaries in our analytic sample (over 80 percent) had a first diagnosis of diabetes (Table III.2). Osteomyelitis was a distant second; less than 12 percent of the analytic sample had this diagnosis.

HBO use was relatively rare before the model start, with just over 5 percent of the analytic sample receiving HBO at some point. There was some variation in the likelihood of HBO utilization among the diagnosis groups. Beneficiaries with a first diagnosis of soft tissue radionecrosis were most likely to receive HBO (almost 17 percent of beneficiaries), while beneficiaries with a first diagnosis of actinomycosis were least likely to receive HBO (only 0.5 percent of these beneficiaries received HBO). Beneficiaries with diabetic lower extremity wounds had a 6 percent HBO use rate.

Among beneficiaries receiving any HBO, the beneficiaries received similar numbers of treatments and incurred similar levels of expenditures for HBO treatments across the diagnosis groups. In general, however, the time from the first observed diagnosis in the claim record to the first HBO session varied across the diagnosis groups. For three of the five groups (diabetic lower extremity wounds, chronic refractory osteomyelitis, and actinomycosis), part of the documentation required for establishing medical necessity is evidence that conventional treatment modalities had been tried and were found to not be effective.

Beneficiaries with diabetic wounds and with actinomycosis experienced the longest gap in time between diagnosis and first HBO treatment, with average gaps of 220 days and 363 days,[23] respectively. Both of these conditions are slow to develop and have many treatment options that can be tried before resorting to HBO. The other conditions had gaps that were roughly half as long. In all cases, though, most beneficiaries who received HBO did so within a year of their qualifying diagnosis appearing on a claim.

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[22] Thirteen percent of beneficiaries included in our study population had more than one diagnosis. Of these, nearly all of the beneficiaries had only two diagnoses.

[23] The high average gap among beneficiaries with actinomycosis was due to a single beneficiary with a gap of over 1,000 days.

Table III.2. HBO utilization by first diagnosis

Condition	Number of beneficiaries with first diagnosis	Number (and percentage) of beneficiaries with condition who used HBO during study period	Average number of days of HBO treatment per user	Average annual HBO expenditures per user	Average annual total Medicare expenditures per user	Average time from diagnosis to first HBO treatment (days)
Any included condition	231,466	11,695 (5.5%)	34.38	$1,988	$45,972	182
Diabetic lower extremity wound	187,298	8,017 (5.5%)	33.99	$1,940	$50,786	220
Osteomyelitis	25,548	1,723 (6.7%)	35.29	$2,043	$45,696	125
Soft tissue radionecrosis	9,645	1,616 (16.8%)	36.36	$2,226	$27,409	69
Osteoradionecrosis	5,370	321 (6.0%)	29.45	$1,714	$24,868	105
Actinomycosis	3,605	18 (0.5%)	31.67	$1,879	$48,544	363

Note: Table includes information on first included diagnosis of beneficiaries with any included condition in all model and comparison states, 2012 to 2017.

HBO = hyperbaric oxygen

3.   Utilization and expenditures

We next generated descriptive figures to illustrate how utilization and payments changed during the study period. Figures III.1 and III.3 present unweighted, unadjusted beneficiary-level HBO utilization and payment outcomes for beneficiaries with diabetic lower extremity wounds.

In these figures, utilization of HBO appears to decline in both model and comparison states in the three years before the model took effect. Part of this decline is mechanical, affected by one data limitation and one choice we made in selecting our study population. First, our claim record is truncated—we only observe diagnoses from January 2012 and later. In the early years of our analysis, the first observed diagnosis is likely not the first diagnosis the patient received. We are therefore capturing beneficiaries with more advanced disease and higher likelihood of receiving HBO therapy. As the study period continues, the new beneficiaries included in the study population may be receiving their first diagnosis of a qualifying condition, and therefore be at earlier disease stages. Second, in order to observe the long-term impacts of the HBO prior authorization model, we include beneficiaries in the study population until they leave an included state, die, or exit FFS Medicare. While some of the included conditions are chronic, some may resolve with time, and we may therefore be including beneficiaries in the sample who no longer have a qualifying condition. To remove the influence of this second factor, we generated these graphs using only one year of data for each beneficiary after the qualifying diagnosis. We observed similar patterns, indicating that our long-term inclusion criterion is not responsible for the observed decline. We cannot distinguish the contributions of the truncated claim record and of a decline in utilization in evaluating the downward trend.

In Figure III.1, we observe an approximately 50 percent drop in utilization in the model states in the two quarters after the model begins, which represents a departure from the overall downward trend. In the following quarters, utilization continues to decrease at a rate closer to the baseline. The utilization rate appears to stabilize by the end of our study period. Prior to model implementation, the probability of HBO utilization was higher in model states than in comparison states. The trend lines cross during the intervention period, and the utilization rate is

lower in model states after implementation. We see a similar pattern in Figure III.2, which presents trends in utilization among beneficiaries with any condition requiring prior authorization.

We also observe a departure from the pre-model trend in the form of a steeper decrease in HBO utilization in the comparison group after model implementation, although it is not as large as the drop in the model states, possibly due to lower baseline utilization. This finding may be the result of general industry trends in HBO use but could suggest the possibility of some contamination of our comparison group. This could be due to changes in MAC operations that spilled over from the model states to the comparison states. (We noted this possibility in Chapter II). In the interim report, we assessed the risk of spillovers that may affect our results. Our analysis led us to conclude that these effects were either not very large or not present at all and that our comparison group was appropriate. However, in the event that there were more substantial spillover effects than we believe is the case, our regression models may have underestimated the true impact of prior authorization.

Since the decline in utilization and expenditures occurs in both model and comparison states, our multivariate analyses detect an additional decrease in the model states over what would be expected given the general trend. One potential concern we note is that difference-in-differences requires parallel trends in the model and comparison states to isolate the impact of the model. While not determinative, visual inspection suggests that both the utilization and expenditure trends observed here appear largely parallel, with the exception of a sizeable increase in the comparison states in quarter 10 (see Figures III.1 and III.2 for utilization, Figures III.3 and 4 for expenditures). This increase partially closes the gap between model and comparison states in the pre-model period. Before and after quarter 10, however, both the utilization and expenditure trends in the model and comparison states appear parallel until the model start. To the extent that the trends are truly different, our multivariate analyses could overstate the impact of the model.

Figure III.1. Probability of HBO utilization among beneficiaries with diabetic lower extremity wounds, by quarter
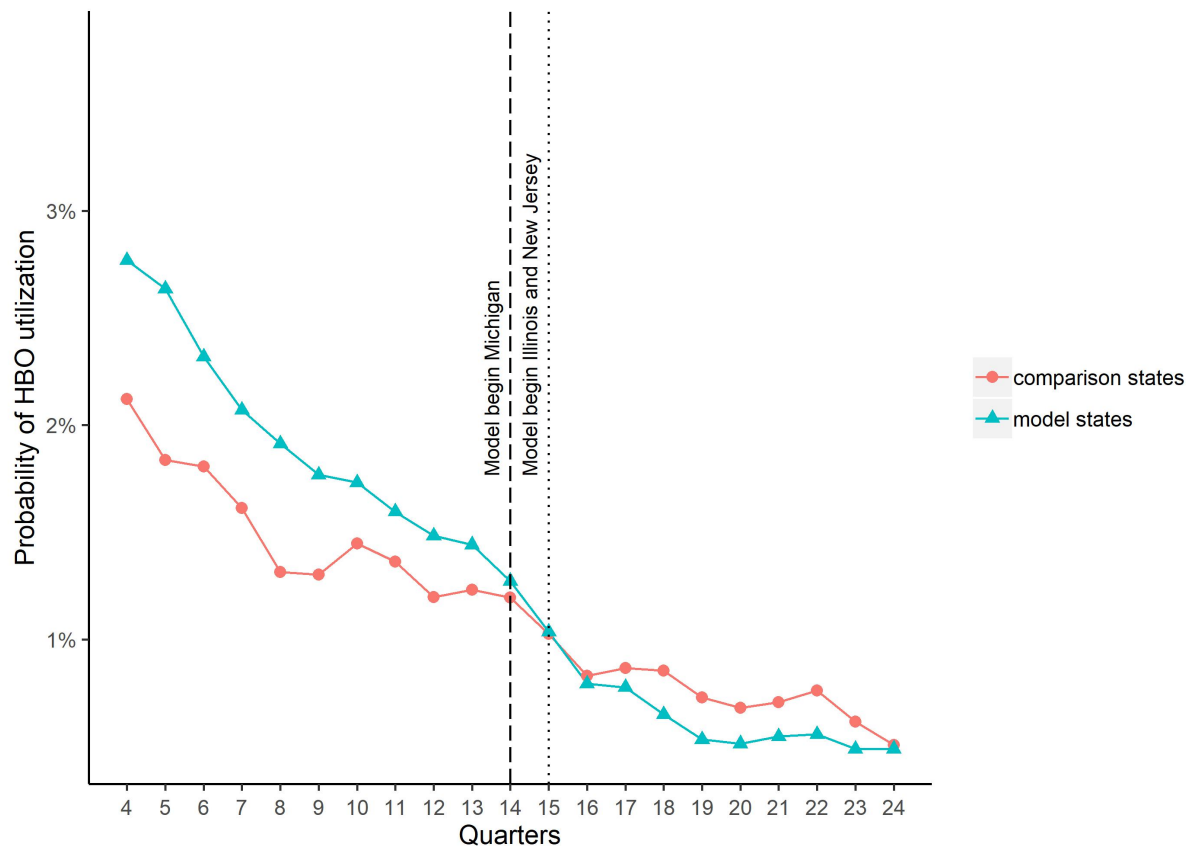
Source: Medicare FFS claims from October to December 2012 (Q4) through October to December 2017 (Q24).

Note: Figure shows HBO utilization during the year following the first diagnosis of diabetic lower extremity wounds in the model and comparison states, from 2012 to 2017. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

FFS = fee-for-service; HBO = hyperbaric oxygen.

Figure III.2. Probability of HBO utilization among beneficiaries with any included condition, by quarter

Source: Medicare FFS claims from October to December 2012 (Q4) through October to December 2017 (Q24).

Note: Figure shows HBO utilization during the year following the first diagnosis of any included condition in the model and comparison states, from 2012 to 2017. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

FFS = fee-for-service; HBO = hyperbaric oxygen.

Figure III.3. HBO expenditures per beneficiary with diabetic lower extremity wound, by quarter
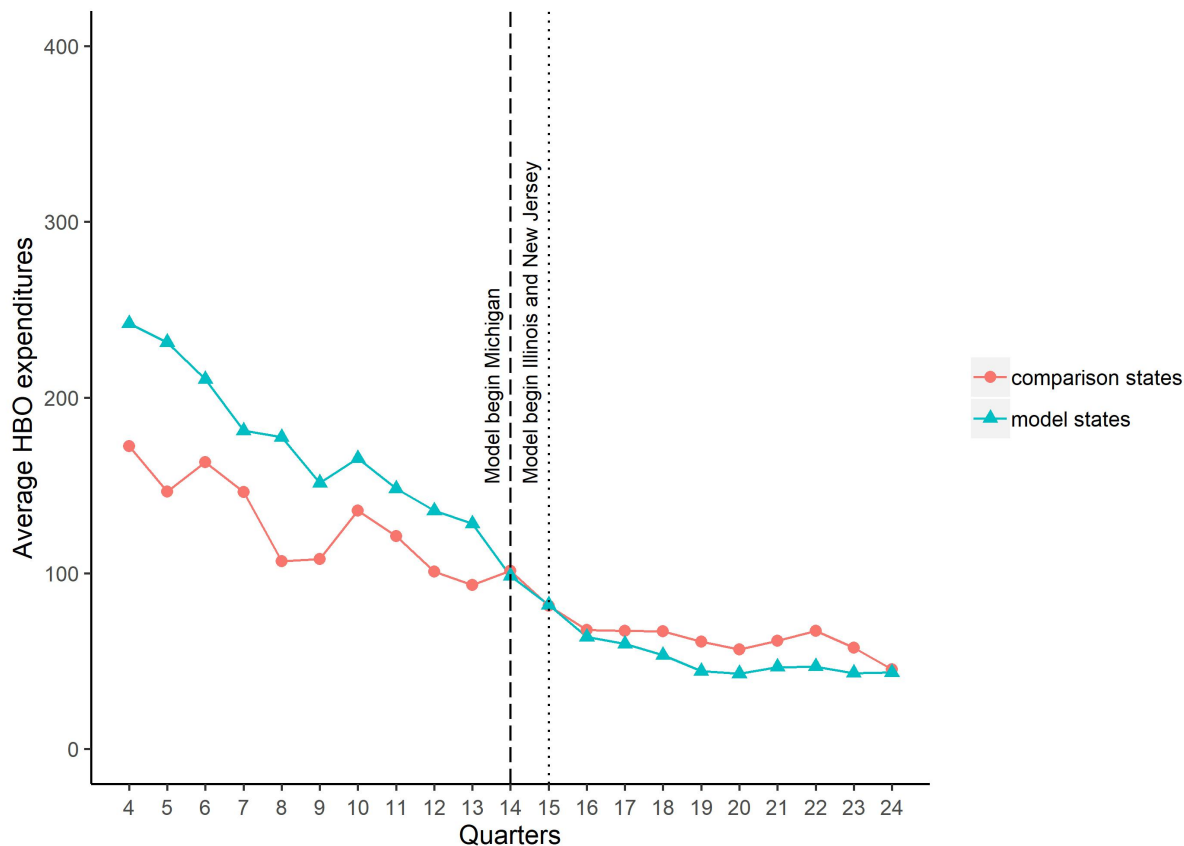
Source: Medicare FFS claims from October to December 2012 (Q4) through October to December 2017 (Q24).

Note: Figure shows HBO expenditures during the year following the first diagnosis of diabetic lower extremity wounds in the model and comparison states, from 2012 to 2017. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

FFS = fee-for-service; HBO = hyperbaric oxygen.

Figure III.4. HBO expenditures per beneficiary with any included condition, by quarter
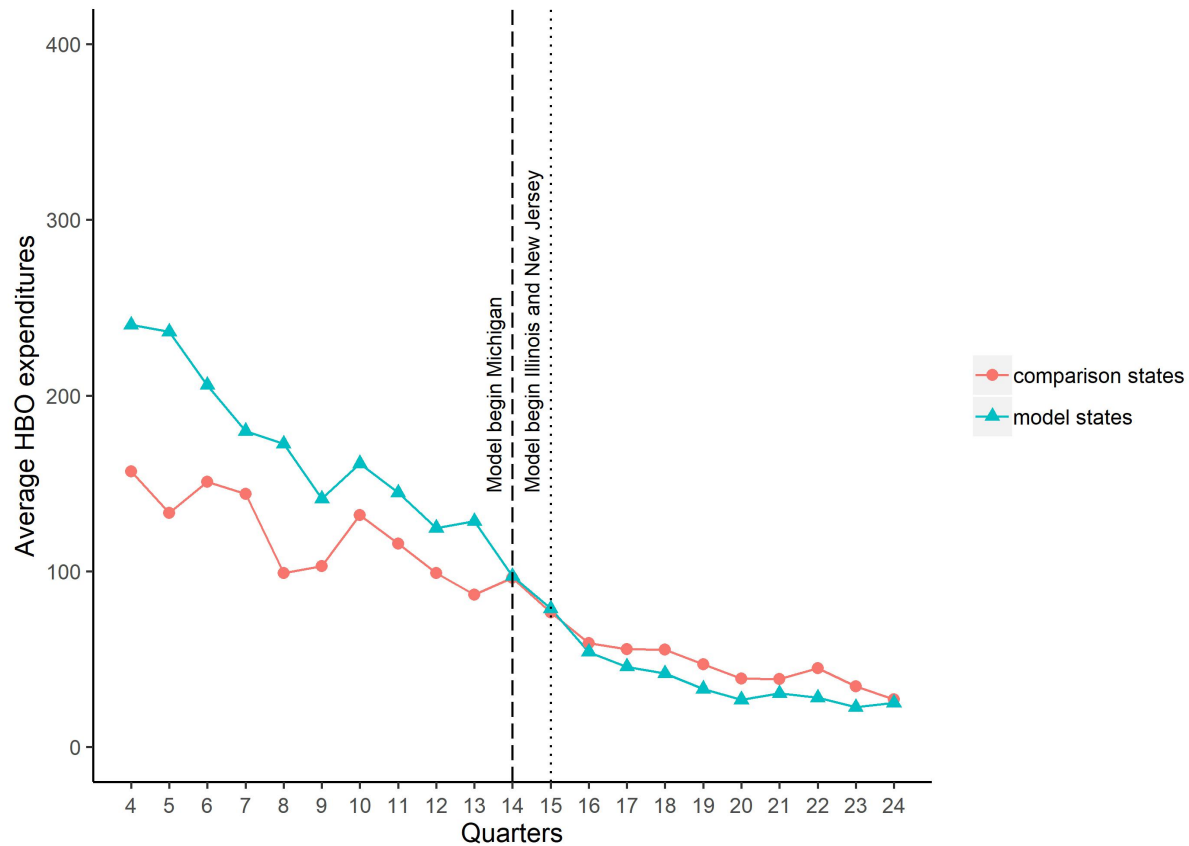
Note: Figure shows HBO expenditures during the year following the first diagnosis of any included condition in the model and comparison states, from 2012 to 2017. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

FFS = fee-for-service; HBO = hyperbaric oxygen.

As shown in Figure III.3, average HBO expenditures among beneficiaries with diabetic lower extremity wounds also saw a discontinuous decrease from before the start of the model to after, over and above the existing downward trend. We see a similar pattern of a decrease in Figure III.4, which presents trends in expenditures for HBO treatment of beneficiaries with any included condition. In the period before model implementation, average HBO expenditures were higher in model states than in comparison states. After implementation, expenditures in model states decreased relative to expenditures in comparison states, such that expenditures became higher in comparison states.

The next subsection describes how we used multivariate analysis to build on these aggregate descriptive analyses to examine HBO utilization and expenditures and arrive at a more complete assessment of the impacts of prior authorization. (Appendices E and F provide power calculations and describe the precision of the analyses.) We included FFS beneficiaries whose claims histories indicated a condition subject to prior authorization for HBO treatment.

Individuals were included in the analysis sample from the date of their first diagnosis until their death, departure from the state, or exit from FFS (see the full description in Chapter II).

B.　Multivariate analysis

Before weighting, beneficiary demographic and health characteristics differed moderately between the model and comparison groups, but our weighting procedure reduced these differences substantially (Appendix B, Tables B.1a and B.1b). The largest remaining difference was that beneficiaries in model states had HCC scores that were between 5 percent and 6.5 percent higher than the scores of beneficiaries in comparison states. We control for HCC score in our regression models to account for this difference. The distributions of the five conditions in the two sets of states were comparable. Due to CMS's selection criteria for model states that deliberately targeted the areas of greatest HBO use, FFS beneficiaries in model states who met the study's condition criterion had approximately 20 percent higher quarterly utilization of and 30 percent higher expenditures for HBO services before implementation of the model (Appendix B, Tables B.2a and B.2b present baseline levels of utilization and expenditure).

1.　Utilization and Expenditures

a.　Beneficiaries with diabetic lower extremity wounds

We estimated that the prior authorization model significantly reduced the utilization of and expenditures for HBO treatments. Table III.3 presents the estimated average marginal effects of prior authorization for several of the key utilization and expenditure outcomes for beneficiaries with diabetic lower extremity wounds: changes in the probability of receiving HBO services, number of HBO treatments, and Medicare payments for these services. Relative to the comparison group, the quarterly probability that beneficiaries with diabetic lower extremity wounds would receive HBO services declined by 0.3 percentage points from a baseline mean of 2 percent (Column I, $p < 0.001$), for a 16 percent decrease. The average number of HBO treatments declined by 0.10, for a 25 percent decrease (Column II, $p < 0.001$). This decrease is smaller than the 50 percent decrease observed in the unadjusted trend lines due to controlling for the simultaneous decrease in comparison states and the adjustment for observable characteristics.

When we examined the impacts of prior authorization by state,[24] we found that New Jersey experienced the most substantial decline in HBO utilization and number of HBO treatments among beneficiaries with diabetic lower extremity wounds. The effect of the model in New Jersey was a 0.5 percentage point reduction in the quarterly probability of HBO utilization (Column I, $p < 0.001$), or a 22 percent decrease. Illinois and Michigan experienced smaller but also statistically significant decreases. We also tested whether the three state-specific coefficients were equal to each other to determine whether we could conclude that the impact of the model in New Jersey was different from the impacts in the other states.[25] We found that the effects of the

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[24] Balance between each model state and the full set of comparison groups was generally good (less than 0.1 standard deviations), with one exception. The New Jersey beneficiaries in our sample all lived in an urban area, meaning that the balance between rural and urban was worse for our state-specific regression models. For Illinois and Michigan, the differences with the comparison group remained below 0.2 standard deviations, but for New Jersey the difference in means remained quite large (13 to 14 percentage points).

[25] A test that failed to reject the null hypothesis of joint equality would indicate that the states experienced statistically the same impact and only the overall impact estimate should be considered.

model indeed differed by state. As noted earlier, the MAC for New Jersey used more strict local coverage determination rules in how they implemented the model and had almost twice as high a non-affirmation rate (see chapter IV). Both of these factors likely contribute to the greater estimated impact of the model in New Jersey.

Table III.3. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with diabetic lower extremity wounds

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (IV)
Overall impact				
Average marginal effect	-0.3***	-0.10***	-59***	216
(Standard error)	(0.04)	(0.02)	(10)	(184)
Baseline	1.9	0.39	169	15,847
Change from baseline (percent)	-15.7	-24.9	-35.0	1.4
R^2	0.07	0.01	0.01	0.27
State-specific impact				
Average marginal effect, Illinois	-0.2***	-0.03	-14	498*
Change from baseline (percent)	-12.9	-9.7	-11.3	3.4
Average marginal effect, Michigan	-0.1*	-0.04	-44***	-98
Change from baseline (percent)	-6.6	-9.4	-25.9	-0.6
Average marginal effect, New Jersey	-0.5***	-0.15***	-130***	206
Change from baseline (percent)	-21.9	-31.6	-58.5	1.2
R^2	0.07	0.01	0.01	0.27
Test state coefficient equality, p-value	0.00	0.00	0.00	0.00

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I), negative binomial (II), and OLS (III and IV) regression analyses using 1,391,110 beneficiary-quarters with diabetic lower extremity wounds for dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, and HCC score. Standard errors were clustered at the beneficiary level. Coefficients from logistic regressions were transformed into average marginal effects. The model states were Illinois, Michigan, and New Jersey. The comparison states were Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

FFS = fee-for-service; HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

We further found that Medicare expenditures for HBO decreased as a result of prior authorization for beneficiaries with diabetic lower extremity wounds. Average quarterly expenditures on HBO services per beneficiary with diabetic lower extremity wounds decreased by $59 more in model states than in the comparison states, for a 35 percent additional decrease (Column III, $p < 0.001$). Our estimate of the change in total Medicare FFS expenditures was not statistically significant, which could be explained by the relatively low rate of HBO use and the fact that the study population is clinically complex, with large variations in total expenditures of which HBO comprises only a small share (Column IV).[26] When we examined total expenditures by state, we found a statistically significant ($p < 0.05$) estimated increase of $498 per beneficiary per quarter in Illinois. As we had done earlier, we tested whether the state-specific coefficients were different from each other, and found that they were. We also estimated an increase in New Jersey, whereas in Michigan our estimate of the impact was negative. However, neither estimate for these states was statistically significant.

b.   Beneficiaries with any of the five included conditions

Among beneficiaries with any included condition, we found similar results to those observed in the diabetic leg wound group (Table III.4).[27] The estimated probability of HBO utilization decreased by 0.3 percentage points (Column I, $p < 0.001$) for a 17 percent decrease and the average number of HBO treatments decreased by 0.14 percentage points (Column II, $p < 0.001$) for a 34 percent decrease. Given that over 80% of the combined group comes from the diabetic subsample, this consistency is not surprising.

When we examined the impacts of the model by state, we again found that New Jersey experienced the greatest declines in HBO utilization and number of HBO treatments.[28] The effect of the model in New Jersey was a 0.6 percentage point reduction in the quarterly probability of HBO utilization among beneficiaries with any condition subject to prior authorization (Column I, $p < 0.001$), or a 25 percent decrease. Illinois and Michigan each experienced a smaller, yet significant, decrease of 0.2 percentage points. As mentioned previously, one potential explanation for the differential impacts by state is that the MAC responsible for adjudicating claims and PARs in New Jersey (Novitas Solutions) used a local coverage determination that was stricter than the NCD used by the MACs in Illinois and Michigan. New Jersey also had the highest baseline rate of HBO utilization (not shown), so it is possible that there was a greater opportunity to reduce unnecessary utilization there than in the other states. Another possibility is that, having implemented a previous prior authorization model for RSNAT, the New Jersey MAC had the infrastructure and capability to implement HBO prior

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[26] Another factor that might add to the total variation in Medicare FFS expenditures is the possibility that our inclusion criteria draw in beneficiaries at early disease stages. Increased variation would reduce our power to detect small changes in total Medicare FFS expenditures.

[27] We also estimated impacts for the group of beneficiaries with any of the four included conditions other than diabetic lower extremity wounds. Our estimates were similar in sign to the estimates for the full group of conditions, but generally statistically insignificant. We estimated a 15 percent decrease in HBO utilization that was statistically significant for the full group, and HBO utilization and expenditures decreased significantly for New Jersey. The overall and state-specific estimates for total Medicare FFS expenditures were not statistically significant.

[28] We again tested whether the coefficients for each state were different from each other.

authorization more rapidly.[29] Finally, our definition of "urban," which relies on attributing zip codes to MSAs, classifies all beneficiaries in New Jersey with the included conditions as urban. Among beneficiaries with conditions subject to prior authorization, urban beneficiaries experienced larger impacts than rural beneficiaries (see below), which may not be fully controlled for in this model specification.

Average HBO expenditures declined by an estimated $56 per beneficiary per quarter (Column III, $p < 0.001$), a 32 percent decrease. The magnitude, significance, and percentage changes in these outcomes were similar to those estimated for the population of beneficiaries with diabetic lower extremity wounds. New Jersey had the largest drop in expenditures on HBO services among beneficiaries with any included condition, at $115 per beneficiary per quarter (Column III, $p < 0.001$). Michigan and Illinois experienced more modest decreases. Our estimate of the change in total Medicare FFS expenditures was again positive, although not statistically significant at conventional levels. Only Illinois experienced a statistically significant increase in total Medicare expenditures ($430, or 3 percent of baseline expenditures). Our estimates for the other states went in the same direction as the estimates from the diabetic lower extremity wound subpopulation and were not statistically significant.

Table III.4. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with any included condition

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (IV)
Overall impact				
Average marginal effect	-0.3***	-0.14***	-56***	194
(Standard error)	(0.04)	(0.02)	(10)	(165)
Baseline	2.0	0.40	173	15,216
Change from baseline (percent)	-16.8	-34.2	-32.2	1.3
R^2	0.10	0.02	0.01	0.27
State-specific effects				
Average marginal effect, Illinois	-0.2***	-0.06*	-14	430*
Change from baseline (percent)	-10.9	-17.9	-10.5	3.0
Average marginal effect, Michigan	-0.2***	-0.07**	-46***	-123
Change from baseline (percent)	-10.1	-17.9	-26.4	-0.8
Average marginal effect, New Jersey	-0.6***	-0.21***	-115***	249
Change from baseline (percent)	-24.7	-44.9	-53.7	1.5
R^2	0.10	0.02	0.01	0.27
Test state coefficient equality, p-value	0.00	0.00	0.00	0.00

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I), negative binomial (II), and OLS (III and IV) regression analyses using 1,696,219 beneficiary-quarters with any included condition on dates of service from April 2012 through December 2017. Control variables included

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[29] We cannot determine with the existing data and analysis whether either of these explanations holds, or whether the New Jersey MAC (Novitas) simply implemented prior authorization differently for reasons unrelated to its previous experience or its use of a local coverage determination.

age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, HCC score, and a set of indicators for included medical conditions. Standard errors were clustered at the beneficiary level. Coefficients from logistic regressions were transformed into average marginal effects. The model states were Illinois, Michigan, and New Jersey. The comparison states were Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

FFS = fee-for-service; HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

We repeated our analyses, stratifying by rural residence and dual eligibility for Medicare and Medicaid among the two beneficiary groups examined. Utilization and cost impacts were larger among urban beneficiaries than among rural beneficiaries in both magnitude and percentage terms. The results by rural stratification are shown in Appendix B, Table B.3a. For both diagnosis groups, impacts were larger among non-dual eligible beneficiaries than among dual eligible beneficiaries. We present the dual eligibility stratified results in Appendix B, Table B.3b.

2. Quality of care

The quantitative analysis for quality of care attempted to assess the impact of the HBO prior authorization model on beneficiary outcomes related to quality of care and adverse outcomes. In order to examine the impact on quality of care, we focused on whether prior authorization affected the likelihood that HBO was delivered with physician supervision. HBO with physician supervision is considered best practice. Indeed, Medicare requires that HBO be performed under physician supervision, although separate claims for HBO therapy and physician supervision of HBO therapy may result in difficulty enforcing the requirement. An increase or decrease in supervision would be an indicator of improved or reduced quality in the process of care. In order to assess whether there was an increased chance of observing adverse outcomes under the model, we focused on any increases in emergency department utilization, unplanned hospital admissions, or death. For the subset of beneficiaries with diabetic lower extremity wounds, we also examined emergency department utilization and unplanned hospital admissions with a primary diagnosis of a lower extremity wound, as well as amputations. Before the prior authorization model began, beneficiaries in treatment and comparison states were comparable on these measures of quality of care and adverse outcomes, although with slightly higher rates of emergency department utilization, unplanned hospitalization, and mortality among model state beneficiaries (Appendix B, Tables B.4a–b and B.5 list baseline measures).

a. Beneficiaries with diabetic lower extremity wounds

We did not find that the model was associated with decreased quality of care or increased incidence of adverse outcomes for beneficiaries with diabetic lower extremity wounds (Table III.5). Among beneficiaries with diabetic lower extremity wounds, the proportion of HBO treatments with physician supervision decreased slightly, but the change was not statistically significant at conventional levels (Column I). Among participating states, the biggest decline in the proportion of HBO treatments with physician supervision occurred in New Jersey and was statistically significant. The estimated changes in Illinois and Michigan were smaller and not statistically significant. One caveat with this measure is that we cannot distinguish between HBO services that were rendered without physician supervision and HBO services that occurred with supervision by limited license physicians.

Beneficiaries with diabetic lower extremity wounds are generally a group at very high risk for adverse events. Thirty-nine percent of beneficiary-quarters included an emergency department visit and 31 percent experienced an unplanned hospitalization in the baseline period. We did not find that the model was associated with greater emergency department use, unplanned hospital admissions, or death for beneficiaries with diabetic lower extremity wounds. Indeed, the probability of an emergency department visit and probability of death each decreased significantly more for beneficiaries in model states than in comparison states. One explanation for this unexpected finding[30] could be reversion to the mean from slightly higher baseline rates. The adverse outcome effects were similar in direction and magnitude across model states.

Table III.5. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with diabetic lower extremity wounds

	Proportion of HBO treatments with physician supervision (I)	Probability of emergency department visit (percentage points) (II)	Number of emergency department visits (III)	Probability of unplanned hospitalization (percentage points) (IV)	Number of unplanned hospitalizations (V)	Probability of death (percentage points) (VI)
Overall impact						
Average marginal effect	-0.05	-0.5*	-0.01	-0.2	0.001	-0.2*
(Standard error)	(0.02)	(0.2)	(0.01)	(0.2)	(0.004)	(0.08)
Baseline	0.9	38.9	0.69	31.3	0.46	2.5
Change from baseline (percent)	-5.1	-1.3	-0.8	-0.8	0.2	-3.4
R^2	0.03	0.14	0.08	0.19	0.12	0.10
State-specific effects						
Average marginal effect, Illinois	-0.04	-0.2	0.001	-0.1	-0.001	-0.2
Change from baseline (percent)	-4.4	-0.5	0.1	-0.3	-0.1	-3.1
Average marginal effect, Michigan	-0.01	-0.8*	-0.02	-0.3	0.004	-0.2
Change from baseline (percent)	-1.4	-1.8	-2.1	-0.8	0.9	-3.2
Average marginal effect, New Jersey	-0.15***	-0.6*	-0.002	-0.4	-0.001	-0.2*
Change from baseline (percent)	-16.8	-1.7	-0.4	-1.2	-0.2	-3.9
R^2	0.04	0.14	0.08	0.19	0.12	0.10
Test state coefficient equality, p-value	0.00	0.02	0.25	0.33	0.77	0.13

Note: The table presents average marginal effects and standard errors from weighted logistic (II, IV, and VI); negative binomial (III and V); and OLS (I) regression analyses using 1,391,110 beneficiary-quarters with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, and HCC score. Standard errors were clustered at the beneficiary level. Coefficients from logistic regressions were transformed into average marginal effects. The model states were Illinois, Michigan, and New Jersey. The comparison states were Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

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[30] We are not aware of side effects of HBO treatment that might result in higher emergency department use or hospitalization. As a result, we believe it may be unlikely that reducing utilization of the treatment would reduce adverse outcomes such as emergency department visits and unplanned hospitalizations. We thus interpret the results as rejecting the hypothesis that quality decreased rather than asserting that there was evidence of an improvement.

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.
HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

b. Beneficiaries with any of the five included conditions

Among beneficiaries with any included condition, we found impacts similar to those for the diabetic lower extremity wound group (Table III.6).[31] The proportion of HBO treatments occurring with physician supervision declined slightly, but the change was not statistically significant at conventional levels (Column I). Among participating states, the largest decline in proportion of HBO treatments with physician supervision occurred in New Jersey and was statistically significant, which was not the case in either Illinois or Michigan. We found no evidence of an increase in emergency department utilization, unplanned hospitalization, or death for this group. Similar to the results for beneficiaries with diabetic lower extremity wounds, baseline utilization rates were high (38 percent probability of an emergency department visit and 30 percent probability of an unplanned hospitalization). We found that the probability of an emergency department visit and probability of an unplanned hospitalization each decreased significantly, with consistent impacts across states. Here, too, reversion to the mean is a possible explanation for the unexpected findings.

Table III.6. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with any included condition

	Proportion of HBO treatments with physician supervision (I)	Probability of emergency department visit (percentage points) (II)	Number of emergency department visits (III)	Probability of unplanned hospitalization (percentage points) (IV)	Number of unplanned hospitalizations (V)	Probability of death (percentage points) (VI)
Overall impact						
Average marginal effect	-0.04	-0.6**	-0.01	-0.3*	-0.002	-0.1
(Standard error)	(0.02)	(0.2)	(0.01)	(0.2)	(0.003)	(0.1)
Baseline	0.9	37.7	0.66	30.3	0.44	5.2
Change from baseline (percent)	-3.9	-1.6	-1.0	-1.1	-0.4	-1.8
R^2	0.03	0.14	0.08	0.19	0.13	0.11
State-specific effects						
Average marginal effect, Illinois	-0.02	-0.3	-0.002	-0.2	-0.002	-0.1
Change from baseline (percent)	-2.1	-0.9	-0.3	-0.5	-0.4	-1.2
Average marginal effect, Michigan	-0.01	-0.9***	-0.01	-0.4*	0.001	-0.1
Change from baseline (percent)	-1.0	-2.1	-1.9	-1.4	0.1	-1.9
Average marginal effect, New Jersey	-0.12***	-0.6*	-0.003	-0.5*	-0.004	-0.1
Change from baseline (percent)	-13.3	-1.7	-0.5	-1.5	-0.8	-2.3
R^2	0.03	0.14	0.08	0.19	0.13	0.11
Test state coefficient equality, p-value	0.00	0.00	0.32	0.06	0.79	0.54

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[31] Estimated impacts were also similar among the group of beneficiaries with any included condition other than diabetic lower extremity wounds.

Note: The table presents average marginal effects and standard errors from weighted logistic (II, IV, and VI); negative binomial (III and V); and OLS (I) regression analyses using 1,696,219 beneficiary-quarters with any included condition on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, HCC score, and a set of indicators for included medical conditions. Standard errors were clustered at the beneficiary level. Coefficients from logistic regressions were transformed into average marginal effects. The model states were Illinois, Michigan, and New Jersey. The comparison states were Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

c.   Quality outcomes specific to beneficiaries with diabetic lower extremity wounds

One benefit of selecting beneficiaries with a diabetic lower extremity wound for separate analysis is that we can examine adverse outcome measures specific to this group. In the previous section, we noted that we did not find evidence of an increase in overall emergency department use (in fact finding a decrease). When we examined the rate of emergency department use specific to the treatment of lower extremity wounds, we found a small statistically significant increase (from 0.5 to 0.53 percent). Individual state effects show that the direction and magnitude of change was nearly identical in all three states, and we could not reject the equality of the coefficients on the three state-specific terms, indicating the state-specific effects were statistically equal. The small size of this impact, coupled with the low baseline rate, suggests little impact on quality of care as measured by emergency department utilization.

We also examined hospitalizations for lower extremity wound-related conditions and rates of amputation. Baseline rates for these outcomes were low—0.3 percent for hospitalizations and 2.5 percent for amputations. We did not find that the model was associated with increased rates of either unplanned hospital admissions for lower extremity wounds or amputation for the total sample. When we examined impacts by state, we found a 0.2 percentage point increase in the probability of amputation in Michigan (a statistically significant 6.5 percent increase) while the other two states showed non-significant declines. For that regression we did find that the state-specific effects were statistically distinguishable from one another.

Table III.7. Impact of prior authorization on adverse outcomes related to diabetic lower extremity wounds

	Probability of emergency department visit for lower extremity wound (percentage points) (I)	Number of emergency department visits for lower extremity wound (II)	Probability of unplanned hospitalization for lower extremity wound (percentage points) (III)	Number of unplanned hospitalizations for lower extremity wound (IV)	Probability of amputation (percentage points) (V)
Overall results					
Average marginal effect	0.03*	0.0002	-0.01	-0.0001	0.02
(Standard error)	(0.01)	(0.0002)	(0.02)	(0.0002)	(0.05)
Baseline	0.5	0.01	0.3	0.0004	2.5
Change from baseline (percent)	5.7	3.7	-4.6	-4.5	0.6
R^2	0.06	0.05	0.05	0.05	0.06
Results by state					
Average marginal effect, Illinois	0.03	0.0001	-0.003	-0.0001	-0.04

	Probability of emergency department visit for lower extremity wound (percentage points) (I)	Number of emergency department visits for lower extremity wound (II)	Probability of unplanned hospitalization for lower extremity wound (percentage points) (III)	Number of unplanned hospitalizations for lower extremity wound (IV)	Probability of amputation (percentage points) (V)
Change from baseline (percent)	5.1	2.0	-1.0	-2.7	-1.8
Average marginal effect, Michigan	0.03	0.0002	-0.02	-0.0001	0.2*
Change from baseline (percent)	5.6	4.3	-5.7	-3.5	6.5
Average marginal effect, New Jersey	0.03	0.0003	-0.03	-0.0003	-0.06
Change from baseline (percent)	6.5	5.9	-8.4	-7.7	-2.5
R^2	0.06	0.05	0.05	0.05	0.06
Test state coefficient equality, p-value	0.22	0.54	0.64	0.78	0.02

Note: The table presents average marginal effects and standard errors from weighted logistic (I, III, and V) and negative binomial (II and IV) regression analyses using 1,391,110 beneficiary-quarters with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, and HCC score. Standard errors were clustered at the beneficiary level. Coefficients from logistic regressions were transformed into average marginal effects. The model states were Illinois, Michigan, and New Jersey. The comparison states were Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

HCC = Hierarchical Condition Category.

Appendix B, Tables B.6a and B.6b present results on quality of care and adverse outcomes among beneficiaries with any included condition and with diabetic lower extremity wounds, respectively, stratified by rural residence and by dual eligibility for Medicare and Medicaid. Impacts were similar among rural and urban beneficiaries in both the group with any included condition and the subgroup with diabetic leg wounds. The same was true of dual eligible and non-dual eligible beneficiaries.

3. Claims denials

The purpose of the denied claims analysis was to determine whether prior authorization affected the extent to which HBO claims were denied by the Medicare program. We examined the proportion of submitted claims denied per beneficiary per quarter for HBO facility services.

Claim denials for HBO treatment were uncommon at the beneficiary level. Before the prior authorization model took effect, the average number of HBO claims denied was about 1 per 100 beneficiaries per quarter. Table III.8 shows the results of the quantitative analysis using a regression model that allows for differential impacts over time. We present the average marginal effects of the model in each quarter after implementation. In the first two quarters after implementation, we observed an increase in both the number and proportion of denied claims. However, the claim denial rate appears to revert to the pre-model rate by the third quarter after implementation. This pattern may reflect a learning period during which providers became accustomed to rigorous enforcement of the pre-existing documentation requirements.

Table III.8. Impact of prior authorization on quarterly beneficiary claims denials, by quarter after model implementation

	Beneficiaries with diabetic lower extremity wounds		Beneficiaries with any included condition	
	Number of denied HBO claims (I)	Proportion of HBO claims denied (II)	Number of denied HBO claims (III)	Proportion of HBO claims denied (IV)
Q1 average marginal effect	0.03*	0.09***	0.06**	0.10***
(Standard error)	(0.01)	(0.02)	(0.02)	(0.02)
Change from baseline (percent)	396.6	313.7	667.5	350.6
Q2 average marginal effect	0.01	0.15***	0.02*	0.12***
(Standard error)	(0.01)	(0.03)	(0.01)	(0.02)
Change from baseline (percent)	142.7	496.8	282.0	441.2
Q3 average marginal effect	-0.01	0.02	-0.01	0.02
(Standard error)	(0.00)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-97.1	72.2	-100.3	78.6
Q4 average marginal effect	-0.01	0.02	-0.01	0.01
(Standard error)	(0.01)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-78.6	52.4	-103.8	45.5
Q5 average marginal effect	-0.01	0.01	-0.01	0.00
(Standard error)	(0.01)	(0.02)	(0.01)	(0.02)
Change from baseline (percent)	-85.0	36.4	-103.7	17.5
Q6 average marginal effect	-0.01*	0.01	-0.01*	0.01
(Standard error)	(0.00)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-116.1	41.3	-129.9	20.0
R^2	0.02	0.04	0.02	0.03

Note: The table presents average marginal effects and standard errors from negative binomial (I and III) and OLS (II and IV) regression analyses using 1,391,110 beneficiary-quarters with diabetic lower extremity wounds and 1,696,219 beneficiary-quarters with any included condition on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, HCC score, and a set of indicators for included medical conditions. Standard errors were clustered at the beneficiary level. Coefficients from logistic regressions were transformed into average marginal effects. The model states were Illinois, Michigan, and New Jersey. The comparison states were Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

IV. QUALITATIVE FINDINGS FROM INTERIM REPORT AND FOLLOW-UP INTERVIEWS WITH MACS

We begin our discussion of the qualitative evaluation results with a summary of the findings from the interim report. We then describe the findings from a series of follow-up interviews with MAC personnel and relate the new findings to the interim report to give an overall sense of stakeholder experience with the prior authorization model.

A. Summary of qualitative findings from interim report

Qualitative analyses in our interim report relied on primary data collection from several key stakeholders. First, we conducted structured interviews with Medicare Administrative Contractor (MAC) personnel 12 to 16 months after model launch to more fully understand the experience of implementing the prior authorization model on Medicare program operations. In addition, from April through May 2017, we conducted site visits to HBO facilities in model states. During the site visits, we conducted semi-structured interviews with HBO facility staff and beneficiaries. Next, we fielded an online survey with HBO facilities in model states to help validate the key themes that emerged from interviews and site visits. Lastly, we conducted a semi-structured, in-person interview with three senior staff members from the CMS Center for Program Integrity (CPI), which is responsible for prior authorization efforts. We obtained their assessment of the HBO prior authorization model's implementation, operation, impact, and effectiveness, as well as CMS' reasons for not extending or expanding the model beyond the planned February 28, 2018 ending date. Together, data gathered from MACs, HBO facility staff, CMS CPI staff, and beneficiaries were used to inform our understanding of stakeholders' experiences with and views concerning the model and its operations. This work also supplemented the quantitative evaluation's assessment of the model's ability to reduce improper utilization and costs while maintaining quality and access to care.

In the interim report[32], we found that:

- **Qualitative analysis supported quantitative findings that prior authorization reduced HBO service use and Medicare expenditures.** Both MAC and provider staff reported a reduction in the number of Prior Authorization Requests (PARs) submitted for ineligible beneficiaries, and HBO provider interviews suggest lower levels of utilization in some settings. (We noted in the report, however, and are noting here that the quantitative analysis is the primary approach we use to determine whether use and expenditures are impacted by the model.)

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[32] A prior evaluation report examining six quarters of model experience (Interim Report for the Evaluation of Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO)) is available at https://innovation.cms.gov/files/reports/interimevalrpt-mpa-hbo.pdf.

- **The qualitative analysis supported the quantitative findings that prior authorization did not appear to reduce the quality of care received by beneficiaries or increase adverse events.** Stakeholders did report some delays in beneficiaries receiving timely access to care in the early phases of the model. HBO staff remarked that the number of beneficiaries whose PAR was non-affirmed for HBO therapy based on ineligibility for the service was small, but the number of beneficiaries whose PARs were initially non-affirmed, delayed, and ultimately affirmed was substantial. These same staff members believed that the delay in obtaining final PAR decisions resulted in delayed access to care for some beneficiaries. HBO providers and MAC staff reported that the delays in obtaining final PAR determinations often resulted from missing or inadequate documentation, which became less of an issue over time as providers become more familiar with the pre-existing documentation requirements enforced under the model. Beneficiaries who had been approved for treatment did not report negative effects on access to care or quality of care.

- **Different stakeholders had different views about the implementation of the model.**

  - **MACs reported few challenges.** MAC staff reported efficient and effective model implementation. Overall, MAC staff report no difficulty in meeting PAR turnaround times and managing PAR volume. MAC reviewers reported spending time to help providers understand medical necessity guidelines and pre-existing documentation requirements enforced under the model in the early stages of implementation and report that providers were "learning over time."

  - **HBO providers reported increased burden, concerns about the application of medical necessity guidelines, and challenges understanding pre-existing documentation requirements enforced under the model.** Many of the providers we obtained information from for the project reported increased administrative burden under the model, difficulties in obtaining PAR supporting documentation, and delayed PAR decisions due to insufficient documents and the resulting time required for resubmission and affirmation. In addition, providers perceived that MAC reviewers lacked the depth of clinical knowledge needed to make accurate medical necessity determinations for HBO, that medical necessity guidelines were being applied inconsistently at times, and that both the guidelines and their application were too strict. Providers also perceived having a significant learning curve at model launch and some continuing confusion around the pre-existing documentation requirements enforced under the model.

B. Follow-up interviews with MACs

1. Methodology

In May 2018, after the model ended, we conducted follow-up telephone interviews with staff from the MACs to better understand their final perceptions of the implementation of the three-year HBO prior authorization model on Medicare program operations.[33] Interviewees were staff from the three MACs that implemented the model and reviewed the PARs—National Government Services (NGS) (Illinois), Novitas (New Jersey), and Wisconsin Physicians Service

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[33] In August 2016, we performed the first round of interviews with MAC staff and summarized our findings in the interim report.

(WPS) Government Health Administrators (GHA) (Michigan). We spoke to nine MAC staff across three separate hour-long group interviews (see Table IV.1).[34]

Table IV.1. MAC interview details

	NGS	Novitas	WPS GHA
Interview date	May 16, 2018	May 22, 2018	May 21, 2018
Interviewees[a]	Two staff: Program manager and medical review nurse	Five staff: Provider enrollment staff member, lead clinical nurse reviewer, acting manager of prior authorization department, director of claims and prior authorizations, and project manager	Two staff: Program manager and the clinical lead for medical review

[a]The roles listed in the table reflect interviewees' positions at the time of interview. These staff were key members of their MAC's HBO prior authorization team at the time of model implementation. All nine MAC staff interviewed transitioned into different roles at the conclusion of the prior authorization model.

HBO = hyperbaric oxygen; MAC = Medicare Administrative Contractor; NGS = National Government Services; WPS GHA = Wisconsin Physicians Service Government Health Administrators.

The MAC telephone interviews we performed focused on six key topic areas:

1. MAC staff roles and responsibilities

2. Changes that could have made the prior authorization model easier for MACs to implement

3. Changes that could have made the prior authorization model less burdensome for providers

4. Feedback received from providers about the prior authorization model

5. Impact of the prior authorization model on beneficiaries

6. Ongoing use of procedures, processes, or guidelines after the prior authorization model ended

Questions developed from these key topic areas are outlined in the appendix. These questions were approved by CMS and shared with MAC staff prior to the interview so that they could gather any additional details and metrics if needed for the interview. A summary of these key metrics is provided in Table IV.2, which can be found at the end of this section.

2. Findings

Generally, MAC staff were satisfied with the manner in which the prior authorization model was operationalized and believed that it reduced the utilization of non-medically necessary HBO services, resulting in significant Medicare savings. However, MAC staff did share their opinions and perceptions on a) changes that could have made the prior authorization model easier for MACs to implement, b) changes that could have made the prior authorization model less burdensome for providers, c) provider concerns, and d) whether the model impacted the timeliness and quality of care. MAC staff also provided information their use of procedures, processes, or guidelines from the prior authorization model.

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[34] Interviews were conducted and recorded through WebEx Services. A third-party transcription company transcribed the recorded interviews. Analysis used NVivo software.

a. MAC staff's opinions on changes that could have made the prior authorization model easier for MACs to implement

Staff from all three MACs believed that better preparedness could have made the prior authorization model easier for them to implement. Staff from two of the three MACs reported technology challenges that reduced the efficiency of the program initially. Specifically, systems integration tasks were not completed and key systems features were not rolled out by the model launch date. This delay required MAC staff to use tedious workarounds, conducting manual reporting and matching of claims until the technical issues were addressed. In addition, all three MACs reported that providers universally had difficulty appending the unique tracking number to affirmed claims when billing after February 28, 2018, because Medicare program files did not accept dates later than the model end date. When the MACs discovered this issue, one MAC developed a workaround that could be shared with the other MACs. Staff across all MACs believed that issues like these would have been hard to identify any earlier in the model implementation. Once these issues were identified, they were resolved in a timely manner by CMS and the model continued to operate efficiently.

b. MAC staff's opinions on changes that could have made the prior authorization model less burdensome for providers

Staff from two MACs that performed a test run believed it was beneficial. In the test runs that were performed, MACs asked providers to send in their prior authorization requests (PARs), and the MACs reviewed these to provide constructive feedback to the providers in accordance with the coverage guidelines. These staff believed that the test runs helped providers learn how to work with them and better understand the guidelines for future PAR submissions.

According to staff at all three MACs, more provider education by CMS could have narrowed the gap between the MACs' and providers' understanding of the coverage guidelines. Staff at one MAC mentioned that education focused on the coverage requirements could have ensured that provider understanding aligned with CMS policy. Staff from the second MAC mentioned that CMS provided confidential inter-MAC and intra-MAC information that could have been shared with providers to reduce differing interpretations of the coverage guidelines between the two groups. Staff from the third MAC described reaching out to providers on an individual basis to address their specific submission issues because individualized technical assistance seemed to be the most efficient method for them.

Staff from two of the three MACs indicated that some issues resulted from communication gaps between the provider's billing department and the provider. MAC staff described often directing these two groups to resolve billing documentation issues together, which seemed to improve the completeness of the documentation submitted. MACs ended up educating not only providers but also billing staff about the need to improve their internal communication and transparency in order to submit the proper documentation. MAC staff believed that their efforts directing providers to their own billing staff were beneficial, and that CMS should encourage this communication through the training and education provided by CMS as part of the pre-implementation process of future prior authorization models.

In interviews for the interim report, MAC staff reported that the HBO National Coverage Determination (NCD) may be outdated. Multiple respondents noted this concern and recommended that CMS review the NCD in light of current evidence-based practice, as

treatment protocols change over time based on accumulated research. MAC staff also noted that there are several conditions for which providers believe HBO would be beneficial that are not included in the current version of the NCD, and felt that a review of these conditions for inclusion might be warranted. Given the reliance of the Novitas (New Jersey) Local Coverage Determination (LCD) on the most recent NCD, any updates or revisions would also impact the LCD.

These sentiments regarding the NCD were echoed in these follow-up MAC interviews. Staff from all three MACs believed that there was a significant gap between Medicare's coverage rules and the provider community's views on when HBO therapy was justified based on scientific evidence. The MAC staff noted that this gap caused frustration among providers. Each of the MAC staff we interviewed believed this frustration was rooted in providers' lack of understanding of and difficulty interpreting the NCD. Staff from two MACs suggested that CMS should revise and expand the coverage guidelines in the NCD to help providers better understand the rules, which would lead to greater compliance. Such a change would also decrease the burden of gathering information for the PAR. These two MACs also felt that the NCD was not well written, making it challenging for providers to understand the coverage requirements. For example, a passage from the NCD reads, "Is chronic refractory osteomyelitis unresponsive to conventional medical and surgical management?" MAC staff explained that this language leaves unclear how much management is called for, what documentation is needed, and whether both medical and surgical interventions are required before HBO would be covered. However, staff from the third MAC felt that providers needed to take more time to review and understand the NCD. These staff agreed that providers did not understand the coverage requirements, but felt the lack of understanding could be addressed by educating HBO providers on how CMS interpreted requirements. This third MAC (Novitas) used a more detailed and specific LCD in making PAR determinations, while the other two MACs used the NCD, which some stakeholders perceived to be vague in comparison to the LCD.

Moreover, staff at all three MACs said that providers often sought clarification from MACs themselves on the extent of documentation needed to substantiate patients' diagnoses and medical necessity for treatment. Staff from the second MAC who called for revisions to the NCD suggested that if CMS were to make coverage guidelines clearer, MACs would be able to provide better feedback to providers.

c.   MAC staff's perceptions of provider concerns

In follow-up interviews, MAC staff described provider concerns that PAR reviewers did not have an adequate HBO background. Staff from two of the three MACs said that providers frequently questioned the clinical experience and knowledge of medical reviewers, and believed that the MACs should be using reviewers who were nurses or physicians with significant HBO expertise. In response to these provider concerns, these two MACs indicated that they began to rely more heavily on the expertise of their medical director for oversight and training, to confirm that they were making correct determinations. Similar sentiments related to the background of PAR reviewers arose in the interim report.

While HBO providers believe that MAC PAR reviews were often inconsistent, MAC staff generally disagreed. In both the interviews for the interim report and the follow-up interviews, HBO providers mentioned that feedback from MAC reviewers on submitted PARs was inconsistent, with different reviewers requesting different documentation and clarification. In

their follow-up interviews, staff from the three MACs all indicated that they were familiar with providers' concerns about inconsistent PAR reviews. While most disagreed that the reviews were inconsistent, staff from one MAD did agree. Staff from this MAC thought that the perception of inconsistency was accurate and primarily attributable to staff turnover, which required providers to build working relationships with new reviewers. Once providers got to know the new reviewers and their individual processes, this MAC staff person believed that there were fewer complaints and the reviews went smoothly. This MAC focused attention on encouraging communication between reviewers and providers. Staff from the second MAC did not feel that there was inconsistency in the reviews. They stated that each patient's condition was reviewed individually, and believed that checklists employed in the review process ensured continuity and consistency. Thus, while providers may have perceived inconsistency between reviewers, these MAC staff believed that different PAR outcomes were due to differences in patient conditions and circumstances, not to inconsistent application of the rules. Staff from the third MAC also did not believe inconsistency was a concern. Their belief was based on results from internal consistency reviews. They directed a small group of nurses to work with a senior nurse analyst and the medical director to make decisions as consistent as possible. The medical director would review all non-affirmations to confirm that PARs with similar conditions and circumstances were being affirmed or non-affirmed consistently. Staff at this MAC also indicated that clarifications from CMS on interpreting the NCD may have impacted decisions in the first year of the model. Thus, it was their perception that any inconsistency that did occur were a result of efforts to improve how their work was done.

Overall, MACs felt that providers appreciated the prior authorization process because it let them know when they interpreted the guidelines correctly. Staff from one MAC noted that at the start of the model there were negative sentiments among providers because they felt burdened by the documentation requirements. These MAC staff felt that insufficient provider education about the prior authorization process may have contributed to the initial confusion and dissatisfaction. However, MAC staff noted that once providers recognized that they did not necessarily need to obtain new clinical information to submit PARs, they became more accepting of prior authorization.

d. MAC staff's perceptions on whether the model impacted the timeliness and quality of care

Staff from two of the three MACs stated that they believed that the prior authorization model had no impact on the timeliness and quality of HBO services rendered to beneficiaries. Staff from the third MAC said they believed that there was not enough evidence to reach a conclusion, but they felt that it was possible that smaller providers did not treat some beneficiaries who met medical necessity requirements until receiving approval because such providers did not want to risk submitting a retroactive prior authorization and not receiving reimbursement for services rendered. However, these MAC staff did not claim to have any evidence that providers withheld care.

e. Use of procedures, processes, or guidelines from the prior authorization model

Staff from two out of the three MACs indicated that their MACs continue to use generic procedures and guidelines developed for the prior authorization model, including management processes and activities, infrastructure systems and technologies, and documentation templates. Staff from one of these MACs mentioned that they also continue to use a generic checklist to

help standardize prepayment reviews for all services. Staff from another MAC noted that, while they did not change processes, they updated their documentation storage system because of their experience under the model. Staff from the third MAC (that ceased using prior authorization procedures or guidelines) indicated that since model processes were no longer applicable, they no longer found them useful. Staff at this MAC noted that they would consider using these procedures and guidelines for future prior authorization efforts.

3. Summary of MAC Interview Findings

Overall, our most recent findings about MAC perceptions of the effects of the prior authorization model were consistent with what was reported to us by providers and beneficiaries in the site visits and interviews we performed during Year 2 of the evaluation. MAC staff reported that they implemented the model with few difficulties. Most felt that the model had no impact on the timeliness or quality of HBO services, and they perceived that the model reduced unnecessary HBO use and cost. Staff from all MACs provided recommendations to improve future HBO prior authorization models. These recommendations included performing test runs of the model, educating providers and staff during pre-implementation or the early stages of the model, promoting consistency in reviews through quality assurance both within and between MACs, and updating the NCD to make coverage guidelines clearer for providers. Table IV.2 provides metrics for each MAC related to the HBO prior authorization model.

Table IV.2. HBO prior authorization metrics from MACs

	NGS	Novitas	WPS
Standard processing time for initial PAR submissions	3 to 5 days	4 days	Year 1: 7 days Year 2: 6 days Year 3: 4 days
Estimate of resubmissions	6 resubmissions	Very few	About 6% of total submissions
Top reasons for resubmission	• Unable to obtain necessary documentation • Patient was not treated long enough to support medical necessity	• Did not meet medical coverage requirements outlined in LCD	• Missing documentation • Overutilization
PAR affirmation rate—Year 3 (%)	67%	36.4%	70%
PAR non-affirmation rate—Year 3 (%)	33%	63.6%	30%

MAC = Medicare Administrative Contractor; NCD = National Coverage Determination; NGS = National Government Services; PAR = prior authorization request; WPS = Wisconsin Physicians Service Government Health Administrators.

V. CONCLUSION

The prior authorization model decreased HBO service use and expenditures; however, our quantitative analysis did not find a statistically significant decrease in total Medicare FFS expenditures. In fact, we found a statistically significant increase in Illinois. We did not find quantitative evidence of adverse impacts on quality of care or adverse outcomes for the full study population, although we did find a slight increase in emergency department utilization for lower extremity wounds among beneficiaries with diabetic lower extremity wounds and a slight increase in the rate of amputations in Michigan.

As we noted previously, the MAC for New Jersey used a local coverage determination to guide prior authorization that was more stringent than the NCD. The model appears to have had a more substantial impact on HBO utilization and costs in New Jersey than it did in the other model states. Another explanation for our findings on utilization and cost in New Jersey could involve its almost entirely urban population—estimated impacts for urban beneficiaries were larger than for rural beneficiaries.

The difference in effects across states raises the possibility that national implementation of prior authorization by using only the NCD might not be as successful at reducing utilization and cost as our overall results suggest. At the same time, the model clearly was effective in each of the three states and we cannot be certain that the greater impact observed in New Jersey was due to use of its local coverage determination. New Jersey also had the highest baseline rate of HBO utilization, so it is possible that there was greater opportunity to reduce unnecessary utilization there than in the other states. Given baseline differences between the two groups of states in utilization and cost due to selection of high utilization states for the model, it is difficult to know how large an impact the model would have if scaled nationally.

Findings from our qualitative analysis of telephone interviews with MAC staff generally align with our quantitative findings. Most MAC staff perceived that HBO service use and expenditures decreased without any impact on timeliness of services or quality of care. MAC staff reported being satisfied with the model and believed that providers were also satisfied once they understood CMS' submission and coverage guidelines. MAC staff also perceived that there was a large reduction in Medicare expenditures; the quantitative analysis found decreases in HBO expenditures but did not find total Medicare cost of care reductions.

Staff from all three MACs believed that changes could have been made by CMS to make the model easier for them to implement and less burdensome for providers. These changes include: requiring test runs prior to the model's start to uncover potential system issues as well as to help providers better understand the prior authorization guidelines; educating providers and staff during pre-implementation or the early stages of the model; promoting consistency in reviews through quality assurance both within and between MACs; and updating the NCD to make coverage guidelines clearer for providers. Overall, our findings from these telephone interviews with MAC staff are consistent with what was reported to us by providers and beneficiaries in the site visits and interviews we performed during Year 2 of the evaluation.

A. Study limitations

The primary limitation of our analysis concerns the use of claims data to identify likely HBO candidates and asses the quality of their care. From available claims data, we could not assess condition severity or rate of healing, and could therefore not observe the characteristics that MACs used to judge whether HBO treatment is covered for a given beneficiary. We relied on claims indicating the presence of one of the conditions covered by the prior authorization model, and therefore our study population likely contains beneficiaries whose condition is not (or is not yet) severe enough to warrant HBO. The large variation in total Medicare expenditures, partly due to broad inclusion criteria, may make it difficult to identify any changes in total expenditures attributable to the model. Likewise, our risk-adjustment strategy involved controlling for diagnosis-based condition groups and for HCC scores based on diagnosis codes in claims data and may not account for all relevant clinical factors that might influence the impact of the model. Also, geographic variation in coding practices might therefore have decreased our ability to control for general health risks.

A secondary limitation of our quantitative analysis is that we used a quasi-experimental design. The gold standard for evaluations—random assignment—was not possible for this study because CMS selected states based on pre-model utilization levels. Any quasi-experimental design such as this one could yield distorted estimates of the impacts if the comparison observations were subjected to different unobserved changes than the model group observations. For example, comparison states may have had greater penetration of accountable care organizations or other cost saving initiatives that led to lower rates of expenditure increases for their beneficiaries than for beneficiaries in the model states. Spillover effects from the model to the comparison states could also contaminate our evaluation design. However, our analyses suggested that such concerns were small for this analysis. Our efforts to select a credible comparison group from neighboring states overseen by the same MACs as the model states— with weighting to make the selected comparisons closely match our model states—and our DID regression models likely removed any major sources of bias in the main estimates.

A possible limitation of the quantitative analysis is that our multivariate analyses overstates the impact of the model because model and comparison group trends are not parallel, which is an assumption of the difference-in-differences analysis. While not determinative, visual inspection of the utilization and expenditure trends suggests that both are largely parallel, with the exception of a sizeable increase in the comparison states in quarter 10. This increase partially closes the gap between model and comparison states in the pre-model period. Before and after quarter 10, however, both the utilization and expenditure trends in the model and comparison states generally appear parallel until the model start. To the extent that the trends are truly different, our multivariate analyses could overstate the impact of the model.

A limitation of the qualitative analysis is that it is possible that the views of the staff we interviewed from each of the three MACs that implemented the model was not representative of the experiences and perceptions of all MAC staff. We did select several staff to interview from each MAC and generally found responses by staff within a MAC to be consistent. That said, we cannot be certain that other staff would share the selected staff's perceptions.

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