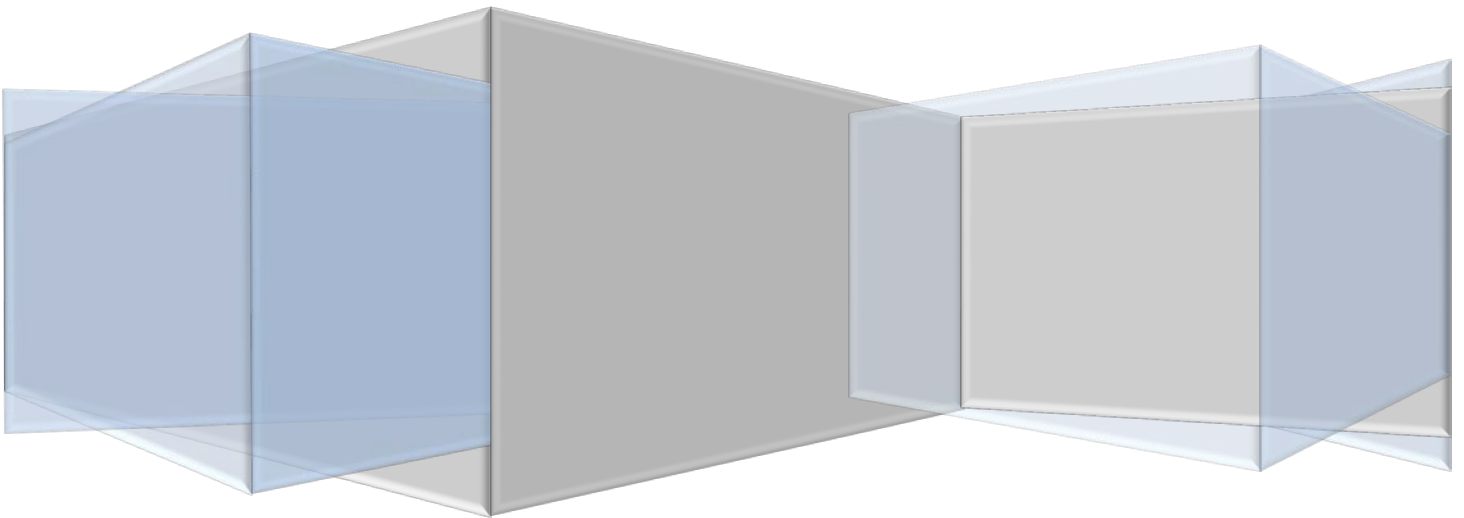




Medicare Part C Utilization Management (UM)

Audit Protocol and Data Request



**Audit Protocol and Data Request
Medicare Part C Utilization Management (UM)**

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UM Audit Protocol

Purpose

To evaluate compliance with regulatory requirements identified in this Audit Protocol and Data Request related to Medicare Part C Utilization Management (UM). The Centers for Medicare and Medicaid Services (CMS) performs UM audit activities in accordance with the data requests, compliance standards, and criteria in this Audit Protocol. CMS may review data, documentation, compliance standards, and/or criteria not specifically addressed in this protocol if it is determined that other related UM or prior authorization (PA) requirements are or may be non-compliant.

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Compliance Standards

Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2024
1.1	Universe Table 1: Utilization Management Criteria	Select up to 20 services or items for review. Sponsoring organization will submit any guidelines, tools, criteria in the format requested by CMS.	
1.2	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review coverage criteria to determine if the Sponsoring organization created or utilized internal criteria that inappropriately restricted a service that is covered under traditional Medicare by applying a more stringent standard than would apply in traditional Medicare.	42 CFR § 422.101(b)(1)-(3)
1.3	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review coverage criteria to determine if the Sponsoring organization created or utilized internal coverage criteria for a service that is fully established under CMS Medicare rules.	42 CFR § 422.101(b)(6)
1.4	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review criteria to determine if the Sponsoring organization created or utilized internal coverage criteria that was not based on current evidence in widely used treatment guidelines or clinical literature.	42 CFR § 422.101(b)(6)
1.5	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review coverage criteria to determine if the Sponsoring organization only created or utilized internal coverage criteria that provided clinical benefits that are highly likely to outweigh any clinical harms when criteria was created to interpret or supplement Medicare criteria.	42 CFR § 422.101(b)(6)(i)(A)
1.6	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review website to determine if internal coverage criteria is publicly accessible.	42 CFR § 422.101(b)(6)(ii)

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Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2024
1.7	Universe Table 1: Utilization Management Criteria	For each sampled service or item with internal coverage criteria that supplements or interprets a Medicare requirement, review website to determine if the Sponsoring organization explained publicly how the additional coverage criteria provides clinical benefits that are highly likely to outweigh any clinical harms in a publicly accessible way.	42 CFR § 422.101(b)(6)(ii)(C)
1.8	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review internal coverage criteria to determine if the Sponsoring organization has evidence that the Utilization Management committee reviewed and approved the internal coverage criteria prior to implementation.	42 CFR § 422.137(b)
1.9	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review criteria to determine if the Sponsoring organization has evidence that the Utilization Management committee reviewed and approved the internal coverage criteria at least annually.	42 CFR § 422.137(d)(1)
1.10	Universe Table 1: Utilization Management Criteria	For each sampled service or item, review internal coverage criteria to determine if the Sponsoring organization has evidence of the UM committee's decisions regarding the development of UM policies in writing.	42 CFR § 422.137(d)(5)

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UM Audit Data Request

Audit Engagement and Universe Submission Phase

Universe Submissions

Sponsoring organizations must submit the following universe (Table 1) comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row.

Descriptions and guidance for what must be included in each data field are outlined in the universe record layout below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

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Please use the guidance below for the following record layout:

Universe Table 1: Utilization Management Criteria (UMC) Record Layout

- Include **all services and items** identified on the CMS List of Targeted Services and complete a separate row for each.
- Enter information based on the current status of the service or item within your organization, taking into account all first tier, downstream, and related entities (FDRs), localities, contracts and/or plan benefit packages (PBPs).
- Enter information in each field (i.e., no blank fields). If the field does not apply to the specific service or item, enter NA.
- Enter information in the specific formatting requested (when applicable).

Column ID	Field Name	Description
A	Name of Service or Item	Enter the name of the Medicare service or item as identified by the CMS List of Targeted Services.
B	CPT and/or HCPCS codes	Enter all CPT and/or HCPCS codes associated with the identified service or item. List codes separated by commas.
C	Fully Established	Does your organization consider the coverage criteria in Medicare for this service or item to be fully established by CMS as defined by § 422.101(b)(6)(i)? Enter Y for Yes if your organization considers the service or item to be fully established in any locality applicable to your organization's service area(s). Enter N for No if your organization does NOT consider the service or item to be fully established in any locality applicable to your organization's service area(s).
D	Fully Established Localities	Please identify all localities applicable to your organization's service area(s) using the two-digit locality code where your organization considers the Medicare service or item to be fully established. For multiple localities, provide all codes using a comma-separated list. Enter NA if you believe this service or item is not fully established in any locality.

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Column ID	Field Name	Description
E	Not Fully Established- No Applicable Medicare Rules (422.101(b)(6)(i)(C))	<p>Did your organization determine the service or item was not fully established because there were no applicable Medicare rules related to the service or item (e.g., regulations, NCDs and/or LCDs)?</p> <p>Enter Y if Yes.</p> <p>Enter N if No.</p> <p>Enter NA if your organization considers this service fully established.</p>
F	Applicable Medicare Regulation(s)	<p>Identify all Medicare regulatory citations applicable to the coverage of, or payment for, the identified Medicare service or item (e.g., 412.3) using a comma-separated list.</p>
G	National Coverage Determination(s)	<p>Enter all associated National Coverage Determinations (NCDs) applicable to the identified service or item (e.g., 220.1) using a comma-separated list.</p> <p>Enter NA if there are no applicable NCDs for this service.</p>
H	Local Coverage Determination(s)	<p>Enter all associated Local Coverage Determinations (LCDs) applicable to the identified service or item (e.g., L34417, L35175) using a comma-separated list.</p> <p>Enter NA if there are no applicable LCDs for this service (within your organization's service area).</p>
I	Not Fully Established- Interpretation Needed	<p>Did your organization determine the service or item was not fully established because criteria was needed to interpret or supplement general provisions in order to consistently render medical necessity decisions, as allowed in § 422.101(b)(6)(i)(A)?</p> <p>Enter Y if Yes.</p> <p>Enter N if No.</p> <p>Enter NA if your organization considers this service fully established.</p>

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Column ID	Field Name	Description
J	Not Fully Established-Flexibility Explicitly Allowed	<p>Did your organization determine the service or item was not fully established because either an NCD or LCD includes flexibility that explicitly allows for coverage in circumstances beyond the specific Medicare indications, as allowed in § 422.101(b)(6)(i)(B)?</p> <p>Enter Y if Yes.</p> <p>Enter N if No.</p> <p>Enter NA if your organization considers this service or item fully established.</p>
K	Coverage Criteria or Guidelines	<p>Does your organization currently utilize or reference any coverage criteria, policies, tools, or guidelines outside of Medicare statutes, regulations, manuals, NCDs or LCDs, that to render medical necessity decisions for this service or item?</p> <p>Enter Y if Yes.</p> <p>Enter N if No.</p>
L	Total Number of Coverage Criteria Policies, Tools, and Guidelines	<p>Enter the number of unique coverage criteria, including policies, tools or guidelines outside of Medicare statutes, regulations, manuals, NCDs or LCDs, that are currently utilized to render medical necessity decisions related to this service or item.</p> <p>Example: if your organization utilizes a third party vendor that has 20 different coverage criteria policies, measures, tools and guidelines related to CT scans, enter 20.</p>
M	Previous Coverage Guidelines	<p>Did your organization create or utilize coverage criteria, policies, tools or guidelines outside of Medicare statutes, regulations, manuals, NCDs or LCDs for this service or item for any portion of the current calendar year (even if not currently used by your organization)?</p> <p>Enter Y if Yes.</p> <p>Enter N if No.</p>

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Column ID	Field Name	Description
N	Vendor	<p>Enter the name(s) of all vendors that your organization utilizes for coverage criteria, policies, tools, or guidelines related to this service or item using a comma-separated list (e.g., MCG).</p> <p>Enter NA if no vendors are utilized.</p>
O	Internal Coverage Criteria Supported by Evidence	<p>Does your organization have documentation to support that all internal coverage criteria for this service or item, including policies, tools, or guidelines, are supported by widely used treatment guidelines or clinical literature?</p> <p>Enter Y for Yes.</p> <p>Enter N for No.</p> <p>Enter NA if there is no non-Medicare criteria or guidelines used for this service or item.</p>
P	UM Committee Approval	<p>Does your organization have evidence that your UM committee reviewed and approved the internal criteria utilized for this service or item prior to the criteria being implemented?</p> <p>Enter Y for Yes.</p> <p>Enter N for No.</p> <p>Enter NA if there is no non-Medicare criteria or guidelines used for this service or item.</p>
Q	Publicly Accessible	<p>Are all internal coverage criteria utilized for this service or item publicly accessible to members, non-members and providers?</p> <p>Enter Y for Yes.</p> <p>Enter N for No.</p> <p>Enter NA if there is no non-Medicare criteria or guidelines for this service or item.</p>

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Column ID	Field Name	Description
R	Website Link	<p>Provide a direct link to the organization webpage where the criteria or guideline(s) can be found.</p> <p>If there are multiple links, please provide all applicable links using a comma separated list.</p>

Audit Field Work Phase

Supporting Documentation Submissions

CMS will select up to 20 services or items for which the Sponsoring organization will be asked to submit all coverage criteria applicable to the identified service or item, including any coverage criteria used by FDRs. Criteria will be evaluated to determine whether the Sponsoring organization is compliant with its Medicare Part C contract requirements. To facilitate this review, the Sponsoring organization must submit the requested coverage criteria. The following information must be submitted upon request:

- All coverage criteria, guidelines, and decision-making tools created or utilized by the Sponsoring organization related to the selected services or items in the universe.
 - All coverage criteria guidelines, and decision-making tools must clearly identify which information is part of a Medicare rule or coverage guideline, and what information is not clearly stated in a Medicare rule or coverage guideline (any additional, interpretive or supplemental criteria).
 - For all criteria that is not clearly stated in Medicare rules or guidelines, evidence that the criteria was based on widely used treatment guidelines or clinical literature.
 - For criteria that interprets or supplements Medicare criteria, a unique and specific statement as to how that criteria provides a clinical benefit that is highly likely to outweigh any clinical harms.
- In addition to all coverage criteria and tools, the sponsoring organization must also submit the Standardized Formatting of Internal Criteria document developed by CMS.
- Documentation, meeting minutes, and notes from the Sponsoring organization's Utilization Management committee, including:
 - Dates of all meetings where UM requirements for the selected service was discussed,
 - Documentation that criteria for the specific service was reviewed and approved before it was implemented (or before 1/1/2024), and
- Documentation of all decisions related to the criteria from the UM committee.

Sponsoring organizations are expected to submit supporting documentation within 15 business days of the request.

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Data Validation

CMS reserves the right to validate the accuracy and completeness an organization’s coverage criteria through one or more of the mechanisms below:

- Review denial notification letters issued during the data request period for sampled services or items.
- Require an organization to participate in webinars in which CMS reviews the organizations’ systems live, including the screen share of coverage criteria, guidelines, and decision-making tools.

CMS may request additional information, including but not limited to a revised universe submission from an organization based on the results of the data validation.

Root Cause Analysis Submissions

Sponsoring organizations may be required to provide a root cause analysis using the Root Cause Template provided by CMS. Sponsoring organizations have two business days from the date of the request to respond.

Impact Analysis Submissions

When non-compliance with UM requirements is identified on audit, Sponsoring organizations must submit each requested impact analysis, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Descriptions and clarifications of what must be included in each submission and data field is outlined in the individual table below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each table. Sponsoring organizations must provide accurate and timely impact analysis submissions within 10 business days of the request. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Impact Analysis Requests

Table 11A: UM Internal Criteria Impact Analysis (UMIC-IA) Record Layout

- Submit the requested information based on the start of the current calendar year (January 1, XXXX) until the date of the audit fieldwork exit conference.
- Pull data for this IA based on when you **processed** a request or determination.
 - The date a request or determination was “processed” may include the date you approved, denied, dismissed, auto-forwarded or otherwise issued a determination.
 - For payment requests “processed” includes the date of payment or notification of denial, or for upheld reconsiderations, the date the case was forwarded to the IRE.

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Column ID	Field Name	Description
A	Service or Item	Enter the name of the service or item as identified by the CMS List of Targeted Services.
B	Internal Criteria	Enter the name(s) of the internal coverage criteria and guideline documents that were determined to be inappropriate.
C	Total Initial Determinations related to Service or Item	Enter the total number of initial determinations processed related to this service or item, regardless of how the organization classified the request, including but not limited to prior authorization requests, concurrent reviews, retrospective reviews, payment reviews.
D	Total Organization Determinations/ Initial Determinations (service or item)	Enter the total number of organization determinations/initial determinations (service or item) processed by your organization related to this service or item. Do not include payment organization determinations.
E	Total Denied Organization Determinations/Initial Determinations (service or item)	Enter the total number of organization determinations/initial determinations (for services or items) denied by your organization related to this service or item. Do not include payment organization determinations.
F	Total denied Organization Determinations/ Initial Determinations Resulting from the use of Inappropriate Criteria and/or Guidelines (service or item)	Enter the number of organization determinations/ initial determinations (service or item) that were denied as a result of the use of inappropriate coverage criteria and/or guidelines for this service or item. Do not include payment organization determinations.
G	Total Organization Determinations/ Initial Determinations (payment)	Enter the total number of organization determinations/ initial determinations (payment) processed by your organization related to this service or item.
H	Denied Organization Determinations/ Initial Determinations (payment)	Enter the total number of organization determinations/ initial determinations denied by your organization related to this service or item.
I	Denied Organization Determinations/ Initial Determinations (payment) Resulting from the use of Inappropriate Criteria and/or Guidelines	Enter the number of organization determinations/ initial determinations (payment) that were denied as a result of the use of inappropriate coverage criteria and/or guidelines for this service or item

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Column ID	Field Name	Description
J	Total Reconsiderations Requests (service or item)	Enter the total number of reconsideration requests (service or item) processed by your organization related to this service or item
K	Denied Reconsideration Requests (service or item)	Enter the total number of reconsideration determinations (service or item) denied by your organization for this service or item.
L	Denied Reconsideration Requests (service or item) Resulting from the use of Inappropriate Criteria and/or Guidelines	Enter the number of reconsideration determinations (service or item) that were denied as a result of the use of inappropriate coverage criteria and/or guidelines service or item.
M	Total Reconsiderations Requests (payment)	Enter the total number of reconsideration requests (payment) processed by your organization related to this service.
N	Denied Reconsideration Requests (payment)	Enter the total number of reconsideration determinations (payment) denied by your organization related to this service or item.
O	Denied Reconsideration Requests (payment) Resulting from the use of Inappropriate Criteria and/or Guidelines	Enter the number of reconsideration determinations (payment) that were denied as a result of the use of inappropriate coverage criteria and/or guidelines.