1275 Pennsylvania Ave. NW
Suite 700
Washington, DC 20009

January 22, 2025

William N. Parham, III
Director
Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request (CMS-10913)

Dear Director Parham:

CVS Health appreciates the second opportunity to comment on the Department of Health and Human Services (Department or HHS), Centers for Medicare & Medicaid Services' (CMS) Paperwork Reduction Act (PRA) notice seeking comments on the annual data submission of Medicare Part C internal coverage criteria and the utilization management (UM) audit protocol data request.

We appreciate CMS addressing our earlier comments, including the clarification to defer both the annual data submission and audits to 2026.

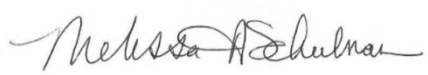
In response to this PRA notice, we ask CMS to reconsider comments previously submitted but not addressed in the materials published on December 23, 2024. Receiving additional clarification on several fields in the UM protocol data request would help CVS Health and other plans understand the intent of each data field, ensuring the accuracy of data collected by CMS.

We also ask CMS to continue to consider the infrastructure and staffing needs required for health plans to comply with these new data requests. We continue to urge CMS to provide health plans with sufficient lead time to prepare and allocate staffing and resources for these new requirements and appreciate modifications made since the original PRA notice.

Thank you for considering our comments and requests. We appreciate CMS' willingness to continue engaging with the industry. We are focused on ensuring any data collection is efficient and results in the reporting of accurate and useful data to CMS to support efforts that promote quality access to care for Medicare

beneficiaries. Please do not hesitate to contact us with any questions about these comments.

Sincerely,



Melissa Schulman
Senior Vice President
Government & Public Affairs
CVS Health

CVSHealth

Comments for Proposed Collection for Medicare Part C Utilization Management (UM) Annual Data Submission and Audit Protocol Data Request (CMS-10913)

Document Title	Page Numbers	Specific Text from Document that is being commented upon	Comment to CMS
Medicare Part C Utilization Management (UM) Annual Data Submission and Audit Protocol Data Request	NA	General Comment	First, we acknowledge and appreciate CMS' ongoing commitment to collaboration, transparency, and burden relief to the industry. We see CMS incorporated several recommendations especially for the annual data submission that will help streamline data collection efforts. In addition, we appreciate the clarification CMS offered regarding internal coverage criteria and service noting inclusion of Part B drugs. Lastly, we appreciate that CMS will defer both the annual data submission and audits to 2026. We do, however, recommend CMS consider the following feedback as part of this 30-day comment window. *Burden Estimate* Because much of the data requested would require manual research and data collections, the CMS burden estimate of 20 hours for the annual data submission and 390 hours for the audit significantly underestimates the number of hours and commitment of resources for this complex data initiative. As such, we recommend CMS conduct a pilot for a select number (i.e., 1 or 2) of services and conduct audits on a small number of plans (i.e., 4-6) rather than the proposed 40 audits. A pilot would allow CMS to initially study and

Document Title	Page Numbers	Specific Text from Document that is being commented upon	Comment to CMS
Medicare Part C Utilization Management (UM) Annual Data Submission and Audit Protocol Data Request	NA	General Comment	understand how plans develop and use such criteria while also affording plans a more manageable data collection effort and if selected, an opportunity to learn and gain an adequate measure of audit experience.
Medicare Part C UM Annual Data Request Utilization Management Annual Submission (UMAS) Record Layout	5-7 5 5	Column ID A – I Column ID A – Criteria Name or Identifier Column ID B – Service Name	We ask CMS to consider the following comments on the proposed UMAS Record Layout. To ensure consistency with other CMS-MOEG universe layouts, we recommend CMS add “Field Type” and “Field Length” to this universe layout. For “Field Length,” we recommend CMS allow for sufficient characters (i.e., 1800 or more) to accommodate potentially lengthy descriptions for these fields.

Medicare Part C UM Annual Data Request Audit Protocol and Data Request	NA	General Comment	We reiterate our recommendation that CMS conduct a pilot for a select number (i.e., 1 or 2) of services and conduct audits on a small number of plans (i.e., 4-6) rather than the proposed 40 audits.
Medicare Part C UM Annual Data Request Audit Protocol and Data Request	4	Compliance Standard Criteria Effective 01/01/2024 Compliance Standard 1.1 *Select up to 20 services for review*.	We ask CMS to confirm that for any audits conducted in 2026, the internal coverage criteria subject to audit will be for plan year 2024 (i.e., retrospective). And if not 2024, please clarify the audit time frame and if the same audit time frame will apply to all plans selected. We ask CMS to confirm that the services selected for review will come from the document "CMS List of Targeted Services," which derives from the Part C UM annual data request. We ask CMS to limit the number of services selected for review, as the more services selected for review, the more personnel and resources will be required for the audit.

	6	Universe Submissions *MAOs must submit an accurate and timely universe within 15 business days of the audit engagement letter date*.	Given the complexity of these data and that much of this data requires manual research and compilation, we recommend CMS allow plans up to 30 business days to generate this universe. Extending the universe submission timeframe will allow plans to conduct necessary quality control and validation, thereby helping to ensure an accurate and complete universe.
Medicare Part C UM Annual Data Request Audit Protocol and Data Request	7-11	Column IDs A – L	To ensure consistency with other CMS-MOEG universe layouts, we recommend CMS add "Field Type" and "Field Length" to this universe layout.

Medicare Part C UM Annual Data Request Audit Protocol and Data Request	7	Column ID A – Field Name: Name of Service	For "Field Length," we recommend CMS allow for sufficient characters to accommodate potentially lengthy descriptions for this field. If CMS selects a Part B drug, we ask CMS to clarify the level of specificity needed for the universe. For example, should separate line items be included for different strengths and dosage forms, or one universe line item at the drug level? If at the drug level, we ask CMS to clarify how plans should populate the universe when different strengths and dosage forms have different internal coverage criteria (i.e., multiple lines in and potential over-representation in the universe).
	7 7	Column ID D –Not Fully Established – No Medicare Rules Column ID D –Not Fully Established – No Medicare Rules	We ask CMS to consider renaming this field to "No Fully Established Medicare Rule." The current name is unclear as to what Yes/No/NA means. We recommend CMS provide an example of when to use "Yes" and "No." The UMC Record Layout with Examples file did not have an example of "Yes." For example, we would think a drug like Keytruda for cancer would be "Y." No LCD or NCD exists for any jurisdiction and there are no applicable Medicare rules other than Chapter 15 50.4.5.
	8	Column ID E – Not Fully Established – Interpretation Needed	We ask CMS to confirm that a response of "Yes" would be appropriate for creation of CAR-T cell coverage criteria based on NCD 110.24. To do this, we would have to interpret the CMS-approved compendia.

Medicare Part C UM Annual Data Request Audit Protocol and Data Request	8	Column ID F - Not Fully Established- Flexibility Explicitly Allowed	We ask CMS to confirm that a response of "Yes" would be appropriate for the following examples: • "Yes" for CAR-T cells based on NCD 110.24: Effective for services performed on or after August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) -i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia. • "Yes" for an LCD that contains language similar to L38920: This policy addresses the off-labeled use of Rituximab for non-anti-neoplastic conditions. The use of Rituximab for labeled indications is covered and not addressed in this policy. Off-label use for anti-neoplastic therapy is not addressed in this policy (see A58113 Off-Label Use of Anti-Cancer Drugs and Biologicals). We have to look in the package insert, A58113, and the CMS-approved compendia to provide a complete list of covered indications.
	8	Column ID F - Not Fully Established- Flexibility Explicitly Allowed	
	10	Column ID I – Previous Coverage Guidelines	We ask CMS to clarify the intent of this field.

Medicare Part C UM Annual Data Request	11	Column ID L – Website Link(s)	We ask CMS to clarify if plans should populate this field with live hyperlinks or would plain text suffice. We ask because multiple active hyperlinks in a document has the potential to cause issues (i.e., increased file size and issues with exporting, slower load times, etc.).
	12	Initial Submission to CMS Review and Data Validation *CMS will attempt to select and review denial letters by searching the MAO's (or their FDR's) electronic systems during a live webinar*.	We ask CMS to provide a timeline between the Initial Submission and the live webinars (i.e., 30 business days).

Audit Protocol and Data Request	12	CMS Review and Data Validation *If CMS is unable to locate denials through a live webinar,* ***we will request a report of denials for selected services*** *(i.e., the 20 targeted services) and then conduct a live webinar to review denial letters*.	We ask CMS to clarify audit scope for the following scenario: If the selected service is a Part B drug and there are no denials and therefore, no denial letters during the audit review period, will CMS then select an additional different service with different internal coverage criteria for review?
	13	Evidentiary Sources Submission: Analysis of Internal Criteria - Column D *Insert the specific language from the Medicare rule (e.g., NCD or LCD) that is being interpreted or supplemented*.	We ask CMS to confirm if the following would be an appropriate response/citation for LCD 38920: • This policy addresses the off-labeled use of Rituximab for non-anti-neoplastic conditions. The use of Rituximab for labeled indications is covered and not addressed in this policy. Off-label use for anti-neoplastic therapy is not addressed in this policy (see A58113 Off-Label Use of Anti-Cancer Drugs and Biologicals). We need to go and gather what is in the package insert, A58113 and the CMS-approved compendia when creating the policy.