United States Government Accountability Office

Report to Congressional Requesters

September 2025

MEDICARE

National Coverage Determinations Are Generally Timely, but Improvements Are Needed

GAO-25-107623

GAO Highlights

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National Coverage Determinations Are Generally Timely, but Improvements Are Needed

GAO-25-107623 September 2025

Highlights of GAO-25-107623, a report to congressional requesters.

Why This Matters

The Centers for Medicare & Medicaid Services (CMS) makes national coverage determinations to grant, limit, or exclude coverage for medical items and services for 68 million Medicare beneficiaries. CMS follows an evidence-based process to determine whether items are reasonable and necessary for prevention, diagnosis, or treatment of an illness or other condition.

GAO Key Takeaways

Requests for national coverage determinations can be made by health providers, organizations, the public or internally by CMS. CMS reviews the requests and prioritizes the analyses to make coverage determinations.

CMS met specified time frames of 9 or 12 months for 83 percent (44 of 53) of the analyses it made determinations for from October 2012 through February 2025. The remaining nine took an additional 6 to 351 days to finalize. We found the agency did not systematically identify the causes of delays when it did not meet specified time frames. Doing so would allow CMS to better monitor its performance and improve timely analyses, which, in some cases, could help Medicare beneficiaries access new or enhanced evidence-based items and services.

According to CMS officials, the agency works with contractors to help mitigate workload and staffing constraint challenges.

Additionally, stakeholders cited challenges related to varied frequencies of CMS's communication about the status of their requests and a lack of transparency about the criteria the agency uses to prioritize requests. CMS officials said they are creating an internal database that would provide requesters with routine updates, but the agency has not made public the criteria used to prioritize requests, leading to stakeholder concerns about transparency.

Example of a Cardiac Pacemaker

Source: Lumos sp/stock.adobe.com. | GAO-25-107623

How GAO Did This Study

We reviewed CMS's Medicare coverage process and other documentation. We also compiled coverage analyses data to report on CMS's ability to meet specified time frames, among other things. We interviewed officials from CMS and other agencies, and requesters and public commenters, who have taken part in the process.

What GAO Recommends

We are making two recommendations to CMS: 1) identify the causes of national coverage determination delays to better ensure that analyses are finalized within specified time frames, and 2) make available to the public the criteria it uses to prioritize its coverage analyses. The Department of Health and Human Services concurred with our recommendations.

For more information, contact: Leslie V. Gordon at GordonLV@gao.gov.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MEDCAC	Medicare Evidence Development and Coverage Advisory Committee
NCD	National Coverage Determinations
TCET	Transitional Coverage for Emerging Technologies

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

September 9, 2025

The Honorable Brett Guthrie
Chairman
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
Chairman
Committee on Ways and Means
House of Representatives

In fiscal year 2024, the Centers for Medicare & Medicaid Services' (CMS) Medicare program spent around $1 trillion—about 15 percent of all federal spending—to provide coverage for health care items and services for approximately 68 million Medicare beneficiaries. Within its authorities, CMS sets national Medicare policies including whether to grant, limit, or exclude Medicare coverage for specific medications, medical devices, including technologies, or services (items and services) to prevent, diagnose, or treat diseases or other conditions.[1] These policies are known as national coverage determinations (NCD).

To make NCDs, CMS has an evidence-based process (coverage process) to determine whether the proposed items or services are reasonable and necessary for the diagnosis and treatment of an illness or injury.[2] Through the coverage process, members of the public, health care providers, or organizations may request coverage or the denial of coverage for specific items or services. CMS officials may also initiate such analyses.

Medicare beneficiaries often rely on timely access to health care items or services that treat life-threatening or irreversibly debilitating diseases and improve quality of life. Federal law and CMS have specified time frames for some steps in the coverage process to help ensure timely NCD

[1]Medical devices include a wide range of products—from implantable pacemakers to wheelchairs—intended to prevent, diagnose, cure, treat, or mitigate diseases or other conditions. See 21 U.S.C. § 321(h).

[2]According to CMS officials, payment policies for NCDs are made after the coverage policy is determined.

decisions.[3] To further expedite the coverage process and encourage transparency, CMS issued a Federal Register Notice in 2013 (2013 Notice) that updated the coverage process, developed alternative ways for items and services to be covered (alternative pathways), and, in 2024, published the National Coverage Analysis Evidence Review Guidance Document. In addition, CMS stated that it prioritizes requests according to "the magnitude of the potential impact on Medicare beneficiaries and staffing resources" and, in more recent years, CMS has placed requests on a publicly available wait list.[4] However, members of the public, beneficiary advocacy associations, congressional stakeholders and others have raised questions about the timeliness and transparency of the process.

You asked us to review the coverage process, including CMS's ability to meet the specified time frames for making coverage determinations. This report examines:

1. the extent to which CMS finalized analyses within the specified time frames and addressed any gaps; and

2. reported challenges in the coverage process and CMS's efforts to address them.

To address both objectives, we reviewed CMS's Medicare coverage process policies, guidance documents, and administrative data. We interviewed officials from CMS, and officials from the Food and Drug Administration (FDA) and the Agency for Healthcare Research and

[3]In total, the time frame for coverage analyses steps is 9 months or 12 months for certain analyses. See 42 U.S.C. § 1395y(l); see 78 Fed. Reg. 48,165 (Notice, Aug. 7, 2013).

[4]See 78 Fed. Reg. 48,164, 48,168 (Notice, Aug. 7, 2013).

Quality (AHRQ).[5] CMS coordinates with FDA on alternative pathways and with AHRQ on some evidence-based reviews.[6]

We also interviewed and obtained information from selected stakeholders, including requesters of NCDs and public commenters. The requesters we interviewed were representatives of seven organizations whose coverage analyses were initiated from October 2019 through February 2025. We selected these requesters to represent variation in coverage process experiences. We chose to focus on October 2019 through February 2025 to increase the likelihood that requesters would be able to remember the details of their interactions with CMS. Further, we interviewed and obtained information from representatives of six associations who submitted public comments about CMS's proposed decisions during the coverage process (public commenters). We selected these public commenters to represent variation in the types of commenters (e.g., industry, beneficiary advocacy, and health condition-specific associations) and coverage pathways (standard or alternative), as well as by the association's geographic reach (state, national or international). We also interviewed representatives from the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)—a panel of experts that CMS convenes to provide independent guidance and advice on clinical topics. The information we gathered from these interviews and written responses is not generalizable.

To examine the extent to which CMS finalized analyses within specified time frames and addressed any gaps, we compiled data from CMS's Medicare Coverage Database—a publicly available database on the CMS website—for analyses finalized from October 2012 through February

[5]On March 27, 2025, HHS announced a restructuring of the department, including merging AHRQ with the Assistant Secretary for Planning and Evaluation to create the Office of Strategy. See Department of Health and Human Services, "HHS Announces Transformation to Make America Healthy Again," (March 27, 2025). Several states have challenged the March 27 directive; litigation is ongoing. See New York v. Kennedy, No. 25-cv-00196 (D.R.I. May 5, 2025). As of September 2025, the transition to a new structure had not occurred; accordingly, we refer to the agency as AHRQ throughout this report.

[6]FDA reviews evidence to determine whether a product is safe and effective, while CMS reviews clinical evidence to determine, among other things, whether the item or service is reasonable and necessary for the Medicare beneficiary population. CMS requires that devices be FDA-approved or cleared as a condition of coverage under the Medicare program, with certain exceptions, though this does not guarantee Medicare coverage.

AHRQ's Technology Assessment Program provides external evidence reviews to CMS to inform its coverage process, including systematic review of the literature and qualitative and quantitative methods of reviewing data from multiple studies.

2025. These data include characteristics about the coverage request and more specifically, the dates at which CMS started or completed a step in the coverage process. We used these data to evaluate the extent to which CMS finalized analyses within specified time frames. We assessed CMS's efforts to address any gaps in its timeliness using key practices for performance management.[7] The key practices include identifying and assessing factors contributing to desired organizational results. To assess the reliability of CMS's coverage process data, we reviewed related documentation, including a data dictionary, interviewed CMS officials about the data, and conducted checks for missing or erroneous data. We also compared these data to CMS Annual Reports to Congress published from 2013 through 2023, as well as to the CMS National Coverage Analysis Status Report, a document that tracks whether analyses are completed or ongoing. We determined that the data were sufficiently reliable for the purposes of our reporting objectives.

To identify reported challenges in the coverage process and CMS's efforts to address them, we reviewed written responses to a structured questionnaire and conducted interviews with our selected requesters and public commenters about their experience with the coverage process. We also interviewed CMS officials and reviewed peer-reviewed articles identified through our background research. We assessed CMS efforts using the policies in the agency's 2013 Notice. Appendix I provides additional details on our scope and methodology.

We conducted this performance audit from June 2024 to August 2025 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicare Coverage Process

The national coverage process starts when a request letter asking CMS to establish, expand, limit, or remove coverage of a specific item or service is formally submitted and accepted by CMS. CMS may 1) accept a request; 2) decline a request; or 3) notify requesters of the need to resubmit a revised request. If CMS accepts a request and issues an

[7]GAO, Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts, GAO-23-105460 (Washington, D.C.: July 12, 2023.)

NCD, the process generally ends when CMS publishes implementation instructions for Medicare Administrative Contractors to use when processing Medicare claims.[8] The entire coverage process can take up to 16 steps, some of which are required by statute, such as conducting evidence reviews, and others that are optional, including holding preliminary, informational discussions with potential requesters.[9] One group within CMS oversees the coverage process, among other responsibilities.

At the core of the 16-step coverage process are the analysis steps, during which CMS staff—generally a team including a medical officer and an analyst—conduct evidence reviews. The team may also include a biostatistician or epidemiologist, depending upon the topic of the analysis. Internal evidence reviews include systematically reviewing relevant clinical research papers, developing a summary of the data, and assessing the validity, clinical relevance, and strength of the clinical research. In the 2013 Notice, CMS updated the process it follows for making an NCD and explained that the analyses steps should take no longer than 9 months—or 12 months if CMS commissions external evidence reviews—starting on the date an analysis is initiated (step 6 below) and ending when the final decision is published (see table 1).[10]

Table 1: Medicare Coverage Process and Analysis Steps

	Step	Coverage process	Analysis steps	Specified time frames
1○	Hold preliminary, informational discussions with potential requesters	✓		
2	Accept or deny initial coverage and reconsideration requests	✓		
3△	Notify requesters of the need to resubmit a request	✓		
4	Prioritize requests	✓		
5△	Update the wait list with accepted requests	✓		
6	Initiate accepted requests or internally initiate analyses and publish tracking sheets on the Medicare Coverage Database–a publicly available database on the CMS website that includes Medicare coverage guidance documents	✓	✓	

[8]There are 16 Medicare Administrative Contractors who are responsible for processing Medicare claims and handling provider reimbursement services, among other tasks in certain geographic areas of the country referred to as jurisdictions.

[9]See 42 U.S.C. § 1395y(l).

[10]See 78 Fed. Reg. 48,164 (Notice, Aug. 7, 2013).

	Step	Coverage process	Analysis steps	Specified time frames
7○	Hold 30-day initial public comment period	✓	✓	
8	Conduct internal evidence review	✓	✓	
9△	Commission external evidence reviews (technology assessments/MEDCAC meeting), including coverage with evidence development (CED) criteria[a]	✓	✓	
10	Publish proposed decision memo, including proposed CED criteria if applicable[b]	✓	✓	6 or 9 months*
11	Hold 30-day public comment period	✓	✓	30 days
12	Publish final decision memo, including CED criteria, if applicable[b]	✓	✓	60 days
13△	Approve CED clinical study	✓		
14	Develop implementation instructions[c]	✓		
15△	Review CED clinical study findings	✓		
16△	Reconsider or remove NCDs older than 10 years[d]	✓		

Legend:

○ = optional steps
△= if applicable

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) documents. | GAO-25-107623

Notes:

*If CMS conducts an internal evidence review, then it has six months to publish the proposed decision memo. If CMS commissions an external evidence review, then it has nine months to publish the proposed decision memo.

[a]External evidence reviews may include, for example, technology assessments–systematic reviews of the evidence conducted by third-party contractors, or consultations with the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC).

[b]CMS may decide to issue a limited coverage national coverage determinations (NCD) with CED study criteria, which is when a promising item or service is covered in a clinical study on the condition that more evidence is collected.

cFor NCDs, groups within CMS coordinate to write and publish implementation instructions for the NCD on the CMS and Medicare Coverage Database websites. Medicare Administrative Contractors use implementation instructions to process Medicare claims.

[d]CMS may conduct internal reviews of existing NCDs that are 10 years or older and may reconsider or retire such NCDs.

During the coverage process, if CMS determines that it does not have the technical or clinical expertise to perform the coverage analysis, due to technical or other complexities, it may commission an external evidence review, such as a technology assessment conducted by a third-party contractor or a MEDCAC meeting to supplement its internal review.[11] The

[11]MEDCAC may review medical literature, public testimony, and technology assessments, for example, to understand the appropriateness of Medicare coverage for an item or service. Additionally, a MEDCAC meeting can be used to inform the broader coverage process or prepare CMS for future requests.

analysis also typically includes two 30-day public comment periods, once after initiating the request and again after publishing a proposed decision. CMS staff review these public comments, and, for the second comment period, provide consolidated responses in their final decisions.[12] See Appendix II for additional information about the coverage process and related activities.

In addition to the 16-step coverage process, CMS has alternative coverage pathways that are intended to expedite coverage decisions, including:

- FDA-CMS Parallel Review, which establishes a process for the FDA and CMS to concurrently review evidence-based data to reduce the time between FDA approval and when CMS publishes its final decision. Two devices were reviewed through the Parallel Review process since it began in 2011.[13]
- Category B Investigational Device Exemption, which allows CMS to provide coverage for a device after the FDA has granted such an exemption.[14] Since it became effective in 2015, CMS has approved 726 clinical studies for Category B Investigational Device Exemption items or services.
- Transitional Coverage for Emerging Technologies (TCET), which is intended to expedite final decisions for certain FDA-designated breakthrough devices by encouraging earlier coordination and discussion between CMS, FDA, and manufacturers.[15] Implemented in 2024, CMS anticipates accepting up to five TCET candidates per year.

[12]The number of public comments ranged from zero to nearly 10,000 for final decisions published from October 2012 through February 2025.

[13]See 81 Fed. Reg. 73,113 (Notice, Oct. 24,2016)

[14]An investigational device exemption refers to an FDA-approved investigational device exemption application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. § 360j(g) and 21 C.F.R. part 812. See 42 C.F.R. § 405.201(b); 78 Fed. Reg. 48,164 (Notice, Aug. 7, 2013).

[15]See 89 Fed. Reg. 65,724 (Notice, Aug. 12, 2024).

National Coverage Determination Coordination

To complete the standard coverage process and alternative pathways, CMS groups coordinate internally and externally with other entities, in addition to working with AHRQ and FDA.

- Various CMS groups determine Medicare benefit categories, payment, and coding for new items and services, among other activities. For example, CMS groups coordinate to ensure that the approved NCDs are assigned to the correct Medicare benefit category, such as physician services.[16] Additionally, one group in CMS assigns codes and payment amounts for newly covered items and services.
- CMS also develops and oversees contracts with external entities to conduct technology assessments and is responsible for approving clinical trial protocols associated with coverage with evidence development.[17]

In addition to overseeing the process for national coverage determinations, the same group is responsible for overseeing and maintaining about 1,000 local coverage determinations—which are established by each of the 16 Medicare Administrative Contractors to specify coverage rules in its jurisdiction—to ensure that they do not conflict with national coverage and payment policies.

CMS Mostly Finalized Coverage Analyses Within Specified Time Frames but Has Not Identified and Assessed Causes of Delays

CMS took a range of about 2 to 20 months to finalize 53 analyses from October 2012 through February 2025. Overall, CMS finalized analyses within the specified time frames for 44 of these 53 analyses. The remaining nine analyses took a range of 6 to 351 more days than the specified time frames for CMS to finalize. These nine analyses that were not finalized within the specified time frames included coverage requests for a cell therapy for cancer, and medical equipment for pain management (see Appendix III for a full list of finalized analyses included in our review).

[16]The broad benefit categories under which an item or service may be covered under Medicare include groupings such as inpatient hospital services, physician services, prosthetic devices, outpatient occupational therapy services, and ambulatory surgical center services.

[17]According to CMS's Coverage with Evidence Development Guidance Document, issued August 7, 2024, the agency collects evidence through coverage with evidence development as Medicare beneficiaries are historically underrepresented in clinical trials due to age and multiple comorbidities, among other reasons.

CMS officials noted the infrequency of delays and attributed them to the COVID-19 national public health emergency and the partial federal government shutdown that occurred from December 2018 to January 2019—during which CMS was unable to coordinate with other Department of Health and Human Services (HHS) agencies. CMS officials also said sometimes new evidence becomes available during internal or external evidence reviews that may lead to longer analyses time frames.

While CMS officials attributed delays to COVID-19 and other factors, we found the agency has not systematically identified and assessed the causes of such delays, which may hinder the agency's ability to better manage the coverage process and prevent future delays. Our review of CMS 2013-2023 Annual Reports to Congress found that while CMS provided data on analysis time frames, it did not identify or assess the causes of the delays. Additionally, CMS officials told us they do not systematically document analysis delays because there are not many delays.

Most Common Types of Medicare Coverage Final Decisions CMS Finalized from October 2012 Through February 2025

The most common types of analyses finalized from October 2012 through February 2025 were implantable devices such as cardiac pacemakers (21 percent), screening and preventive services such as lung cancer screening (17 percent), and imaging services such as magnetic resonance imaging (12 percent).

Source: GAO analysis of CMS data; Lumos_sp/stock.adobe.com (photo). | GAO-25-107623.

Although the number of delayed analyses were infrequent, two of six public commenters we spoke with emphasized the importance of timeliness of each analysis for Medicare beneficiaries who are waiting for final decisions. Specifically, these commenters noted that some of the Medicare beneficiaries for whom they advocate have rapidly deteriorating conditions and would benefit from more analyses finalized within the specified time frames.

As previously discussed, the 2013 Notice states that analyses should take no longer than 9 months—or 12 months if CMS commissions external evidence reviews. Identifying the causes of delays for analyses that exceed this performance goal would be consistent with key practices for agency performance management stated in our prior work.[18] These practices are important to help agencies manage and assess the results of their efforts and include the following:

1. Inform management decisions with evidence, by using what an organization learned from its evidence to help ensure that the organization's activities are targeted at further achieving desired results.

[18]GAO, *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, GAO-23-105460 (Washington, D.C.: July 12, 2023.)

2. Identify any additional evidence needs to further inform decisions, by collecting new evidence that may be needed to better understand challenges that were identified or to monitor the performance of any new or changed strategies or processes.

Identifying and assessing the causes of delays would allow CMS to better monitor its performance and make changes as appropriate to improve the number of timely analyses. This could, in some cases, facilitate access to new or enhanced evidence-based preventive, diagnostic, or beneficial items and services. Additionally, it would improve the predictability of coverage process time frames.

CMS Has Efforts to Mitigate Workload and Communication Challenges, but Has Not Been Transparent About Prioritization of Requests

CMS officials and nine of 13 stakeholders told us that the agency faced challenges with staffing constraints or communication in the coverage process. CMS has ongoing efforts to help mitigate the effects of these challenges. Four of 13 stakeholders also reported a lack of transparency in how CMS accepts and prioritizes requests for initiation as a challenge. CMS officials told us the agency has not yet made such criteria publicly available.

CMS Delays Initiation and Uses Contractors to Accommodate a Growing Workload and Staffing Constraints

CMS experienced a sharp increase in NCD requests starting in fiscal year 2021 while also experiencing staffing constraints. CMS received about 98 coverage requests from fiscal year 2013 through February 2025 with the numbers of requests generally increasing over this time period.[19] Specifically CMS received an average of about seven requests per year from fiscal year 2013 through fiscal year 2020 and an average of 12 requests annually from fiscal year 2021 through February 2025 (see table 2).[20]

[19]This is not an exact number of requests, but an approximation based on information from CMS. According to CMS officials, complete request data for fiscal years 2016 through 2018 are not available; therefore, these years are not included in this calculation.

CMS initiated and finalized 53 analyses of about 98 requests from October 2012 through February 2025. The 45 remaining requests were either not accepted, accepted but not initiated, or not finalized during this period.

[20]According to CMS officials, complete request data for fiscal years 2016 through 2018 are not available; therefore, these years are not included in this calculation.

Table 2: Number of National Coverage Determination Requests Received, Fiscal Year 2013—February 2025

Fiscal year	Requests received
2013	11
2014	6
2015	7
2016	—[a]
2017	—[a]
2018	—[a]
2019	7
2020	6
2021	14
2022	13
2023	15
2024	12
2025[b]	7[b]
Total	**98**

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-25-107623.

Notes:

[a]According to CMS officials, complete request data for fiscal years 2016 through 2018 are not available.

[b]Fiscal year 2025 does not include data for the full fiscal year. The fiscal year 2025 data are from October 2024 through February 2025.

According to agency officials, CMS staffing has been constrained due to the inability to replace staff lost through attrition. Since July 2023, the agency has had a hiring freeze in place, with few exceptions, according to CMS officials. Since December 2024, the CMS group responsible for executing the NCD process has experienced a 22 percent reduction in staff, including medical officers who are key to conducting coverage analyses, according to agency officials. [21] Additionally, they told us they anticipate further staff retirements, including of clinical staff, and potential reductions due to ongoing departmental reorganization efforts.

Four requesters and public commenters similarly observed that limited staffing levels have affected time frames and available expertise.

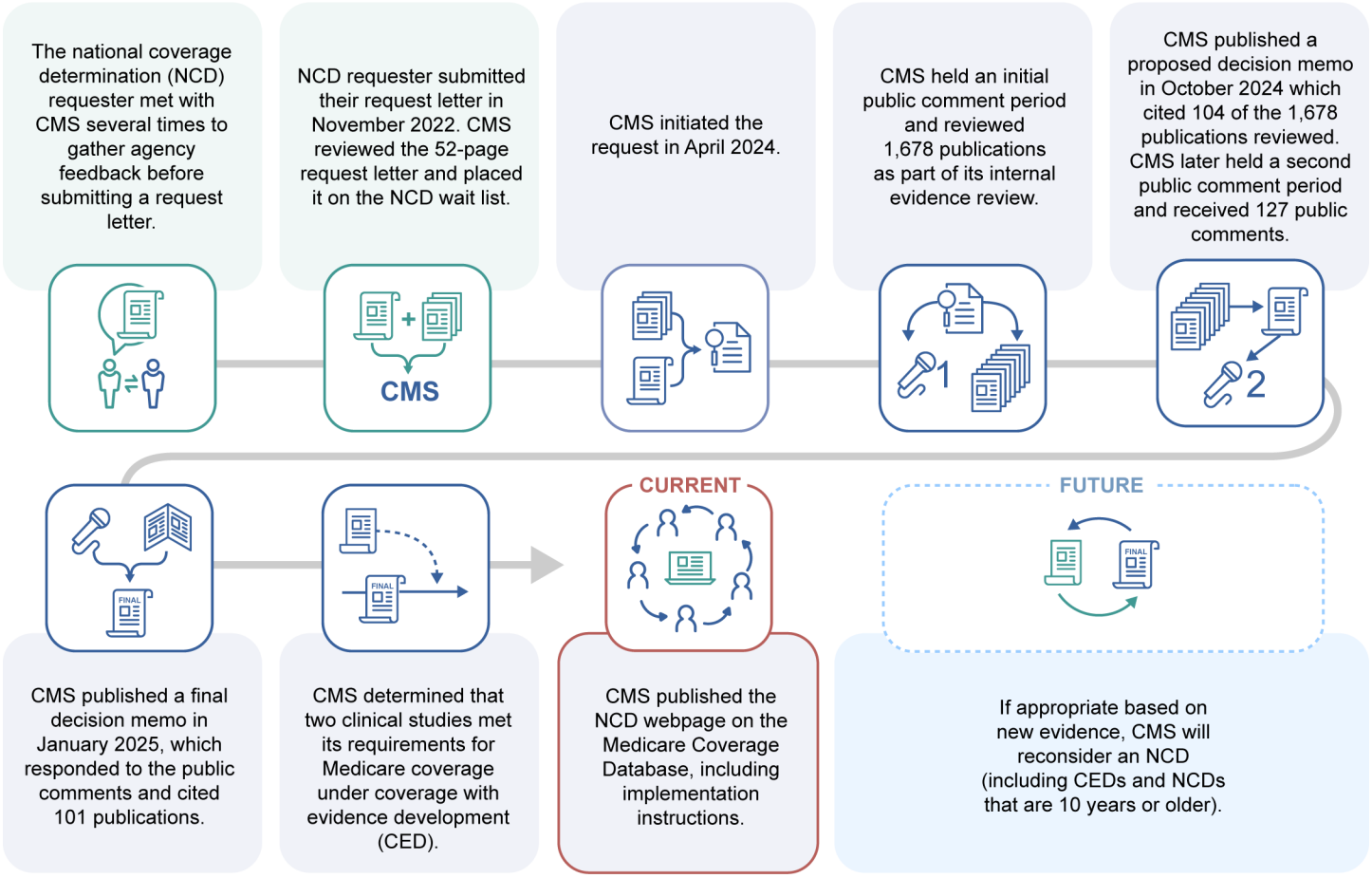
[21]In August 2024, CMS officials said that many of their current medical officers have worked at CMS for decades and several are eligible for retirement.

Specifically, they indicated that, based on their experiences interacting with CMS during the coverage process, the agency has too few staff with the breadth or depth of expertise needed to conduct the coverage process, including analyses. One requester told us that the CMS group responsible for executing the NCD process seems “chronically under-resourced” and limited in their ability to review request letters.

Based on our review of the coverage process, staffing is a key resource needed to conduct the NCD process. As a part of the NCD process, CMS staff undertook internal evidence reviews of clinical research papers, commissioned external evidence reviews, held meetings with clinical experts, and reviewed public comments to finalize analyses and make coverage decisions for 53 of the 98 requests the agency received from October 2012 through February 2025. For internal evidence reviews, CMS cited an average of 65 clinical research papers for each coverage analysis—a total of over 3,400 for the 53 analyses finalized from October 2012 through February 2025. To support the coverage process, CMS also commissioned 46 external evidence reviews during this time frame. Most of the external evidence reviews were commissioned to support the broader coverage process and to prepare CMS for future requests for innovative medical devices or services, such as diabetes management devices and associated clinical measures for these new devices, according to CMS officials. Some were commissioned to directly support specific analyses, such as the analysis for Screening for Lung Cancer with Low Dose Computed Tomography—an imaging procedure.

Additionally, CMS reviewed an average of 340 public comments per coverage request for 53 analyses finalized from October 2012 through February 2025 (18,033 total public comments), as a part of the 30-day public comment period. Lastly, as part of the coverage process, CMS publishes a final coverage decision summarizing responses to these public comments. One requester acknowledged that while the comment period added time to the analysis, this period was valuable and demonstrated that CMS’s analysis process aimed to include multiple stakeholder perspectives. Another requester said CMS staff had written the best summary of analysis on a requested medical procedure that he had ever seen published. CMS’s analysis of an implantable device to manage a heart condition finalized in January 2025 illustrates its effort to include multiple evidence sources and perspectives (see fig. 1).

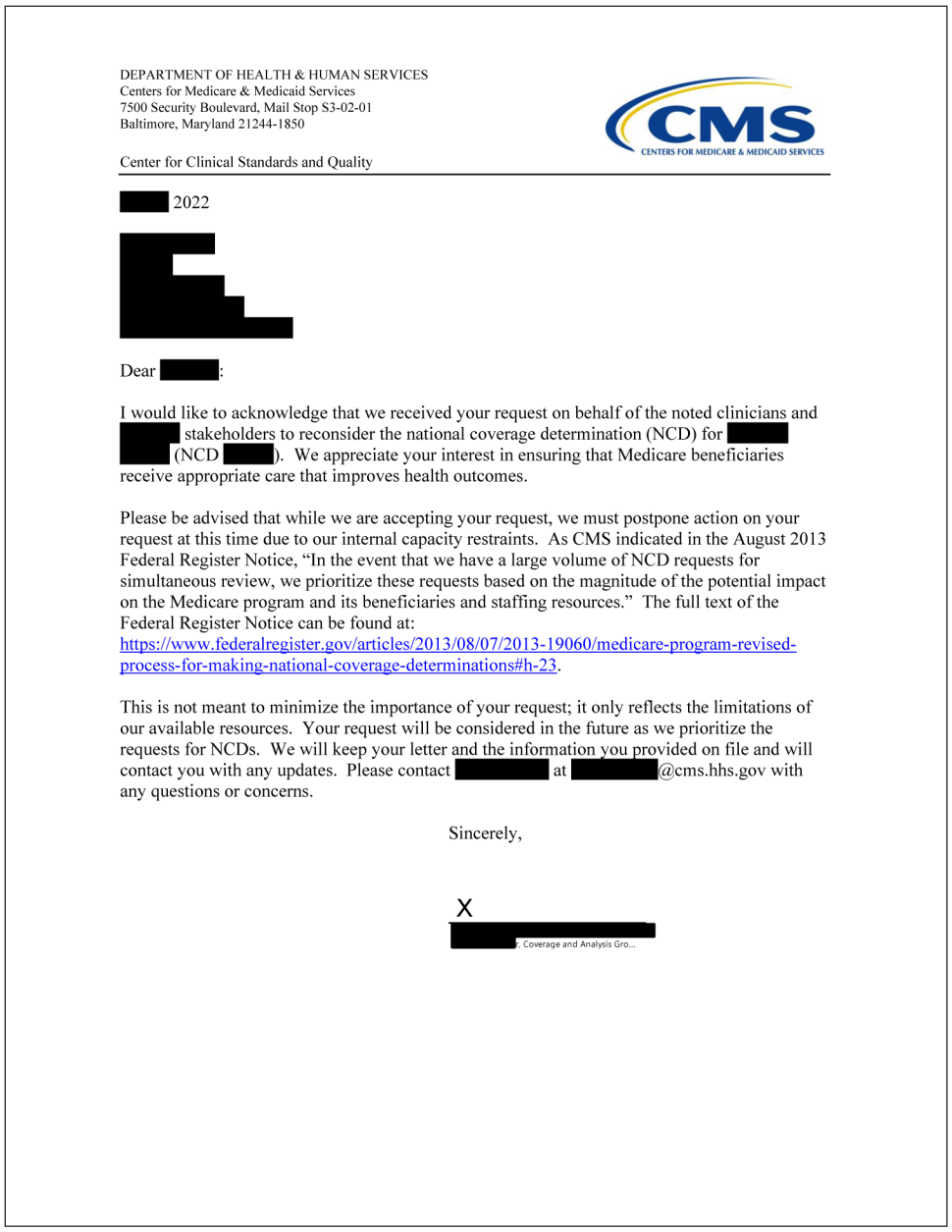
Figure 1: Illustrative Figure of the Coverage Process for Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and stakeholder information; RaulAlmu/stock.adobe.com (illustrations). | GAO-25-107623

Agency officials told us that due, in part, to the large volume of NCD requests and constrained staffing, they have had to delay the initiation of some requests and work with contractors to finalize analyses. For example, a requester shared with us a letter they received from CMS citing reasons for delaying initiation of their request (see fig. 2).

Figure 2: CMS Letter Notifying a Requester of Postponed Initiation



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

[redacted] 2022

[redacted]

Dear [redacted]:

I would like to acknowledge that we received your request on behalf of the noted clinicians and [redacted] stakeholders to reconsider the national coverage determination (NCD) for [redacted] (NCD [redacted]). We appreciate your interest in ensuring that Medicare beneficiaries receive appropriate care that improves health outcomes.

Please be advised that while we are accepting your request, we must postpone action on your request at this time due to our internal capacity restraints. As CMS indicated in the August 2013 Federal Register Notice, "In the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources." The full text of the Federal Register Notice can be found at: https://www.federalregister.gov/articles/2013/08/07/2013-19060/medicare-program-revised-process-for-making-national-coverage-determinations#h-23.

This is not meant to minimize the importance of your request; it only reflects the limitations of our available resources. Your request will be considered in the future as we prioritize the requests for NCDs. We will keep your letter and the information you provided on file and will contact you with any updates. Please contact [redacted] at [redacted]@cms.hhs.gov with any questions or concerns.

Sincerely,

X
[redacted], Coverage and Analysis Gro...

Source: Centers for Medicare & Medicaid Services. | GAO-25-107623

In an effort to keep requesters better informed, CMS began publishing a wait list on a quarterly basis in its NCD Dashboard in 2023.[22] The list includes accepted requests that CMS intends to, but has not yet, initiated. The NCD Dashboard helps to provide greater transparency into the early stages of the coverage process, according to agency officials.

Also, as of December 11, 2024, CMS officials stated that they started working with a contractor to conduct external evidence assessments for requests processed through TCET. TCET is the newest coverage pathway intended to expedite final decisions for certain FDA-designated breakthrough devices by encouraging earlier coordination and discussion between CMS, FDA, and manufacturers.[23] This approach will allow medical officers and analysts to focus on the standard coverage process, according to CMS officials. Consequently, officials say, CMS intends to increase the number of all analyses, including TCET, completed each year. In addition, CMS officials also said they are working to identify a more efficient way to reconsider or remove NCDs older than 10 years, of which there are currently 350—CMS may decide to revise or retire such NCDs based on the evidence and clinical practice. Currently, CMS must reconsider each NCD individually, which officials said is not efficient given their limited staffing and existing workload. CMS staff said the agency is working to determine if it can develop an alternative approach that is both expeditious and legally sound.

CMS Has Taken Steps to Improve Communication with Requesters and Set Request Letter Expectations

Selected stakeholders who provided information to us through our questionnaire or interviews identified some challenges with communication and request letters. For example, two requesters told us that they had little to no interaction with CMS staff, even at key milestones, such as when CMS accepted the NCD request. CMS officials acknowledged that communication during the coverage review process could be improved.

In contrast, five of seven NCD requesters we interviewed found CMS's communication to be timely and appreciated CMS's staff responsiveness to questions when prompted by requesters. Three of six public commenters we spoke with told us they appreciated CMS staff's

[22]CMS officials said the agency published its first wait list in 2020 and began publishing on a roughly quarterly basis beginning in 2023.

[23]In a Federal Register Notice, CMS stated that the agency anticipates receiving about eight TCET pathway requests per year and analyzing approximately five each year. See 89 Fed. Reg. 65,724 (Notice, Aug. 12, 2024).

willingness to meet and generally found their meetings with CMS staff helpful and informative, while one other public commenter characterized their meeting as a listening meeting. Four of six public commenters said they met with CMS officials, including the CMS Administrator and other staff, numerous times before submitting their comments.

Two of the seven requesters we spoke with largely characterized the request submission process as burdensome and mentioned the need to hire consultants, which were costly. For example, a requester we spoke with told us their organization hired a consultant for more than $250,000 over a 2-year period to work with CMS while their request moved through the coverage process. Specifically, two requesters told us they often did not understand CMS's expectations of request letters.

Similarly, CMS officials said they sometimes found it challenging to determine what was being requested. For example, CMS officials said that they often could not discern the requesters' goals from the information included in the request letter—whether they were requesting to establish, expand, limit, or remove coverage of an item or service. According to CMS, some of the 98 requests CMS received from October 2012 through February 2025, were not accepted because they lacked information CMS needs to fully understand the request or support a national coverage analysis.

To improve communication with requesters of NCDs, in December 2024, CMS officials said they are beginning to develop a new internal database that, in future phases of development, will allow them to automatically notify the requester of approaching or completed milestones. For example, CMS said that the new database could alert requesters about 30-day due dates for public comments. According to CMS documentation, the agency anticipates incorporating coverage process steps into the new internal database in fiscal years 2025 and 2026.

CMS's internal standard operating procedures state that CMS staff may meet with requesters and public commenters at any time before, during, or after the coverage process, with the lead analyst serving as the agency's point of contact to the public. Further, according to these procedures, the lead analyst or medical officer should communicate with stakeholders at the following points:

1. If a request is not accepted, the lead analyst should offer to schedule a meeting with the requester either before or after a formal letter is sent notifying the requester of this decision.

2. For accepted requests, the lead analyst is responsible for sending an email notification to the requester with a formal letter notifying the requester of this decision.

3. When a tracking sheet is posted to initiate the analysis, the lead analyst sends the requester an email with a link to the published tracking sheet. The lead analyst is also responsible for sending an email notification to any relevant specialty societies and the Medicare Administrative Contractors.

CMS Requires a "Complete, Formal Request" Before Initiation

Before a request for an item or service is initiated, CMS requires a "complete, formal request." According to CMS's 2013 Federal Register Notice, a "complete, formal request" must include

- a description of the item or service,
- the applicable Medicare benefit category,
- symptoms or conditions for which the item or service may be used,
- whether the item or service is intended for use by providers or beneficiaries,
- scientific evidence supporting the use of the item or service,
- the target Medicare population, and
- information from the Food and Drug Administration, if applicable.

Source: 78 Fed. Reg. 48,164 (Notice, Aug. 7, 2013). | GAO-25-107623

CMS has taken a number of steps to set request letter expectations. Specifically, CMS's website offers information and resources to aid requesters. For example, requesters may access previous request letters on the Medicare Coverage Database to learn more about the information included in similar requests that were accepted. In 2024, CMS published, and made available on its website, the National Coverage Analysis Evidence Review Guidance Document to provide guidance to requesters and stakeholders about how CMS evaluates clinical evidence. CMS officials said that other than the 2013 Notice and this recent evidence review guidance, they had few criteria about what must be included in a request letter.

In addition to their written guidance, CMS staff will meet with potential requesters before they submit a request. Meeting with CMS prior to submitting a request or encouraging applicants to review prior request letters may help facilitate more complete requests and make the agency's reviews more efficient. Although not required, CMS officials said they encourage potential requesters to meet with CMS staff first, because it allows requesters to clarify and tailor requests prior to submitting a request. CMS officials said that a very high percentage of requests include such a meeting.

Criteria CMS Uses to Prioritize NCD Requests Are Not Transparent

CMS officials shared information with us about criteria they use to prioritize requests that are not included in the 2013 Notice or available publicly. Some stakeholders we spoke with told us that this creates a challenge because they do not understand how CMS prioritizes the requests it accepts. According to the 2013 Notice, the agency prioritizes requests "based on the magnitude of the potential impact on the Medicare program and its beneficiaries, and staffing resources."[24] Further, CMS officials told us they prioritize requests related to prevention and screening and requests that improve patient access to particular items or

[24]See 78 Fed. Reg. 48,164, 48,168 (Notice, Aug. 7, 2013).

services, over reviewing requests to remove coverage, though these criteria are not publicly available. The 2013 Notice states that the updated coverage process was expected to provide “clarity and transparency” for the public; however, CMS officials acknowledged that the information in the Notice does not fully convey the agency’s criteria for prioritizing requests.

Four of 13 stakeholders told us that they do not understand how CMS decides which requests to initiate and in which order, and why some requests are placed on the waiting list. In December 2024, CMS officials said that they have considered creating a document outlining the criteria they use to prioritize or initiate requests and that this type of document would provide the public with a good sense of how they evaluate the potential effect on the Medicare program and its beneficiaries. Subsequently, CMS officials said they had paused consideration for the time being due to staffing constraints and changes in agency priorities.

If CMS makes the criteria it uses to prioritize requests available to the public, including requesters, it would provide greater clarity and transparency and improve requester and stakeholder experiences navigating the coverage process. Also, greater clarity and transparency has the potential to improve the submitted requests and the efficiency of the coverage process.

Conclusions

Completing NCDs within the specified time frames can provide more predictability about coverage decisions for items and services that can improve the health or quality of life for Medicare beneficiaries, particularly those with rapidly deteriorating conditions. While CMS largely makes these decisions within the specified time frames, it has not systematically identified and assessed the factors that contribute to any delays. Having such information and using it to address causes of delays as appropriate could help the agency mitigate any systemic causes of delays. This will be particularly important if CMS continues to experience increased requests under constrained or reduced staffing. In some cases, more predictable and timely finalized analyses may also facilitate access to new or enhanced evidence-based preventive, diagnostic, or beneficial items and services.

CMS has efforts to address its growing workload and improve communication about the coverage process including delaying the initiation of some analyses it accepts, meeting with potential requesters, and developing an internal database that, in future phases of development, will notify requesters of upcoming milestones. However, the

agency does not publish or communicate all the criteria it uses to determine the requests for which it will initiate an analysis and in what order, leading to stakeholder concerns about the transparency of the process. If CMS provides information on all the criteria the agency uses to prioritize requests for initiating an analysis, stakeholders' submitted requests may improve, leading to a more efficient coverage process.

Recommendations for Executive Action

We are making the following two recommendations to CMS:

The Administrator of CMS should identify the causes of any delays in national coverage determinations and take actions, as appropriate, to better ensure that analyses are finalized within the specified time frames. (Recommendation 1)

The Administrator of CMS should make available to the public the criteria it uses to prioritize its analyses of national coverage determination requests. (Recommendation 2)

Agency Comments

We provided a draft of this report to HHS for review and comment. In its written response, reproduced in appendix IV, HHS concurred with our recommendations. HHS also provided technical comments, which we incorporated, as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at GordonLV@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.

//SIGNED//

Leslie V. Gordon
Director, Health Care

Appendix I: Finalized Analyses Time Frames Scope and Methodology

To examine the extent to which the Centers for Medicare & Medicaid Services (CMS) finalized analyses within specified time frames and addressed any gaps, we interviewed CMS officials, reviewed federal law and CMS guidance, and compiled and analyzed data from the Medicare Coverage Database—a publicly available database on the CMS website. We examined the characteristics of analyses finalized from October 2012 through February 2025, including the dates at which CMS started or completed a step in the coverage process, the type of item or service requested and its related condition or disease, and whether external evidence reviews were included in the analysis. We also collected data about the number of clinical research papers reviewed and public comments received for each analysis.

After these data were compiled, we used a multi-step process to examine the timeliness of each finalized analysis. First, we identified the analyses that used external evidence reviews or coverage with evidence development (CED)—and those that did not. Next, we determined whether each finalized analysis met the specified time frames.[1] We made this determination by calculating the number of days it took for CMS to publish its final decision, which is when the analysis is finalized. We determined that CMS made timely coverage decisions if coverage analyses take no longer than 9 months—or 12 months if CMS commissions external evidence reviews—starting on the date an analysis is initiated and ending when the final decision is published.

Of the 16-step coverage process, we examined those with the specified time frames including steps 6 through 12:

- Step 6: Initiate accepted requests or internally initiate analyses and publish tracking sheets on the Medicare Coverage Database.
- Step 7: Hold initial 30-day public comment period.
- Step 8: Conduct internal evidence review.
- Step 9: Commission external evidence reviews (a technology assessment or a Medicare Evidence Development and Coverage Advisory Committee meeting), including CED criteria (if applicable).
- Step 10: Publish proposed decision memo, including proposed CED criteria (if applicable).
- Step 11: Hold second 30-day public comment period.

[1]See 42 U.S.C. § 1395y(l); see 78 Fed. Reg. 48,164 (Notice, Aug. 7, 2013).

- Step 12: Publish final decision memo, including CED criteria, if applicable.

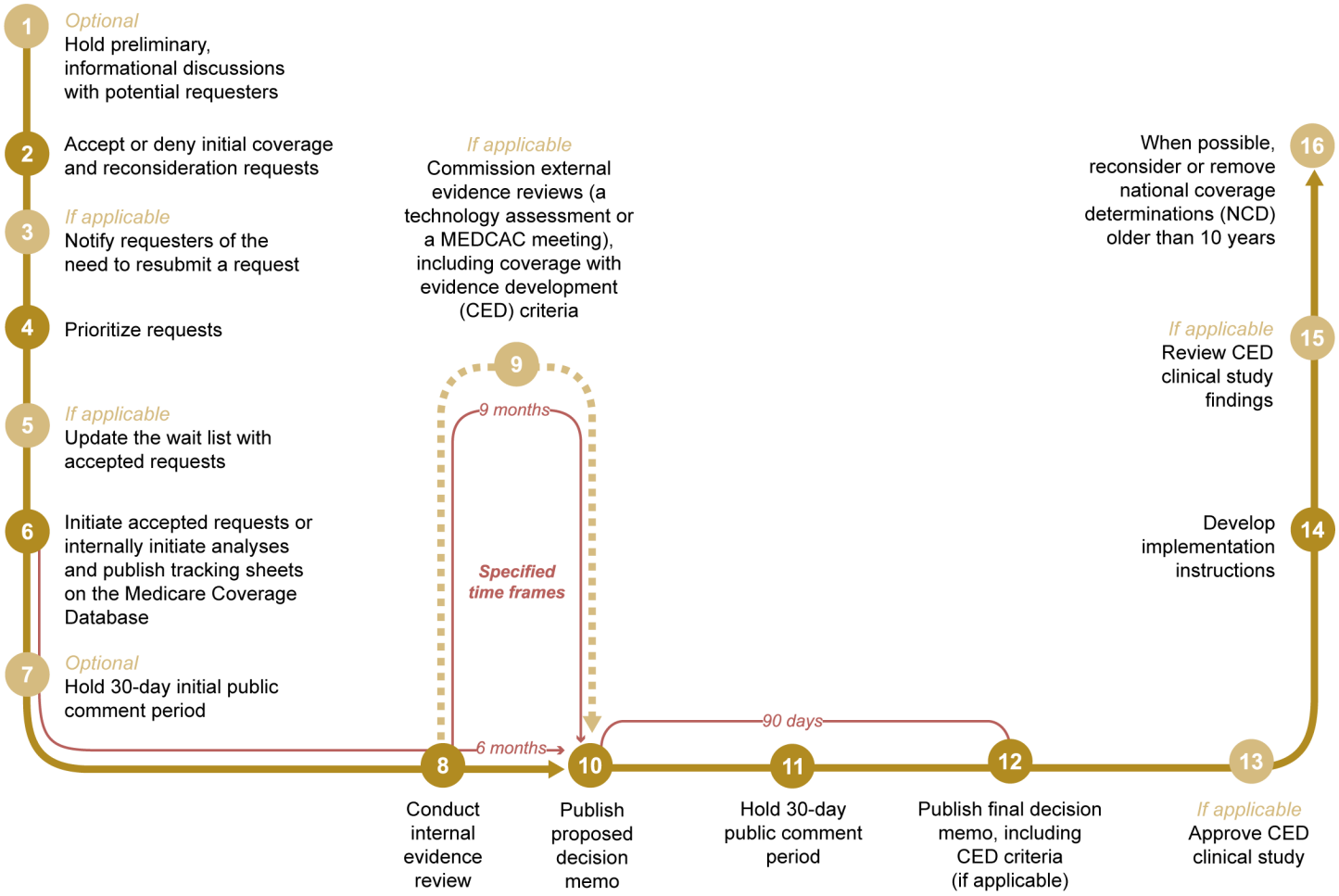
Using our methodology, we identified and examined 53 analyses that CMS finalized from October 2012 through February 2025 and determined which of these were finalized within the specified time frames (for analyses finalized during this time period, see Table 3 in Appendix III). Additionally, we selected the most recent, as of February 2025, finalized analysis published on January 13, 2025, to create an illustrative example of the coverage analysis workflow.

To assess the reliability of CMS's coverage process data, including for finalized analyses, we reviewed related documentation, including a data dictionary, interviewed CMS officials about the data, and conducted checks for missing or erroneous data. In addition to comparing these data to CMS Annual Reports to Congress published from 2013 through 2023, we also compared them to the CMS National Coverage Analysis Status Report, a document that tracks whether analyses are completed or ongoing. We determined that the data were sufficiently reliable for the purposes of our reporting objectives.

Appendix II: Additional Information About CMS's 16-Step Medicare Coverage Process

This appendix provides additional information about the Center for Medicare & Medicaid Services' (CMS)16-step Medicare coverage process (see fig. 3).

Figure 3: CMS's Medicare Coverage Process



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) information. | GAO-25-107623

Notes: See 42 U.S.C. § 1395y(l); see 78 Fed. Reg. 48,164 (Notice, Aug. 7, 2013).

CMS commissions external evidence reviews, which include technology assessments–systematic reviews of the evidence conducted by a third-party contractor–and convenes meetings of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)–to supplement its research. CMS may decide to issue a limited coverage NCD with CED study criteria, which is when a promising item or service is covered in a clinical study on the condition that more evidence is collected.

Step 1: Hold preliminary, informational discussions with potential requesters. CMS encourages, but does not require, requesters to have a preliminary discussion prior to submitting the formal request. During this meeting, the requester may present a summary of the item or service and supporting documentation for the potential request, and the CMS staff identify additional information that may be needed. These meetings may be held in person, virtually, or by phone. There is no explicit time frame for this step.

Step 2: Accept or deny initial coverage and reconsideration requests. CMS receives coverage requests and determines if they are "complete, formal" requests. There is no explicit time frame for accepting or denying initial requests. If CMS issues a national coverage determination (NCD) and new evidence becomes available that may change the NCD decision, requesters may opt to submit a request for reconsideration. In such cases, CMS repeats the full NCD coverage process. CMS noted in its Federal Register Notice in 2013 (2013 Notice) that it typically takes up to 60 days for the agency to accept or deny a reconsideration request.[1]

Step 3: Notify requesters of the need to resubmit a revised request (if applicable). The 2013 Notice states that before a request is accepted, CMS requires a "complete, formal request" that includes sufficient information, including a clearly identified benefit category, supporting evidence and documentation, information on the usefulness and benefit to the Medicare population, and a complete explanation of the design, purpose, and method for using the item or service. There is no explicit time frame for this step.

Step 4: Prioritize requests. For requests that are accepted, CMS's 2013 Notice states that it prioritizes them "based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources."[2] There is no explicit time frame for this step.

Step 5: Update the wait list with accepted requests (if applicable). If CMS cannot initiate the request when accepted, the request is placed on a wait list published on the CMS website (see fig. 4). CMS officials said the agency published its first wait list in 2020 and began publishing on a

[1]See 78 Fed. Reg. 48,164, 48,165 (Notice, Aug. 7, 2013).

[2]See 78 Fed. Reg. 48,164, 48,168 (Notice, Aug. 7, 2013).

roughly quarterly basis beginning in 2023. There is no explicit time frame for this step.

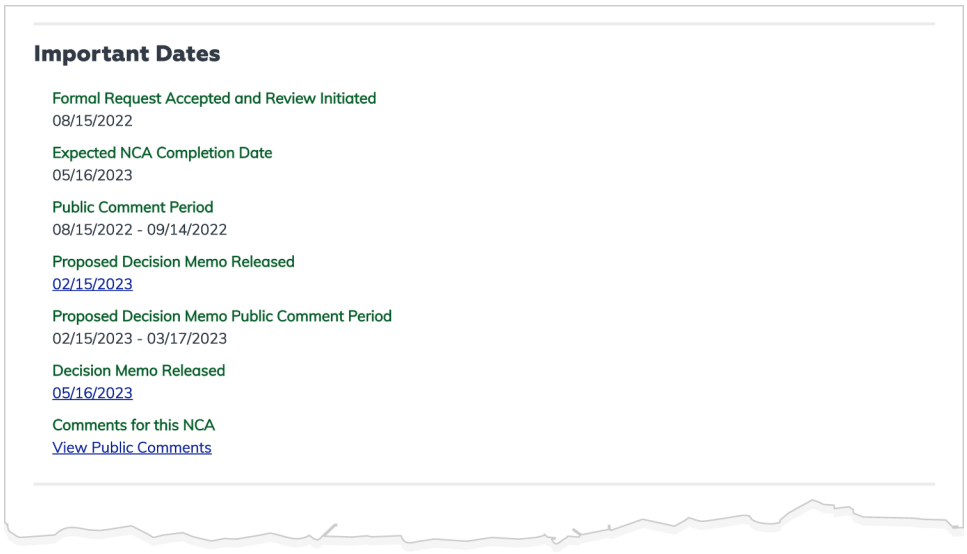
Figure 4: Excerpt from CMS's Medicare Coverage Wait List, May 2025

NCD Wait List
Colorectal Cancer Screening
Diaphragm Pacemakers for Neuromuscular Disease (request for non-coverage)
Hepatitis C Screening
Hyperbaric Oxygen (HBO) Therapy for Radiation Proctitis and Radiation Enteritis
Infusion Pumps - Continuous subcutaneous insulin infusion (CSII)
Latent Tuberculosis Infection (LTBI) Screening
Power Standing Systems
Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing

Source: Centers for Medicare & Medicaid Services, National Coverage Determination (NCD) Dashboard. | GAO-25-107623

Step 6: Initiate accepted requests or internally initiate analyses and publish tracking sheets on the Medicare Coverage Database. After CMS initiates an accepted request or internally initiates an analysis, the agency publishes a tracking sheet on its Medicare Coverage Database website, a publicly available database on the CMS website that includes Medicare coverage documents. (see fig. 5). The dates on the tracking sheet inform stakeholders of key coverage process milestones. There is no explicit time frame for this step.

Figure 5: CMS Sample Coverage Analysis Tracking Sheet



Source: Centers for Medicare & Medicaid Services, Medicare Coverage Database. | GAO-25-107623

Note: NCA = National Coverage Analysis.

Step 7: Hold 30-day initial public comment period. CMS typically provides an initial, optional public comment period after publishing a tracking sheet. CMS uses the initial public comments to inform the proposed decision memo. The dates for this optional public comment period are communicated on the tracking sheet that is published on the Medicare Coverage Database website.

Step 8: Conduct internal evidence review. CMS evaluates relevant clinical evidence to determine whether the evidence is of sufficient quality to support a finding that an item or service within a benefit category is reasonable and necessary for the diagnosis or treatment of an illness or injury. According to the specified time frames, this step must be completed within six months of initiating the review.

Step 9: Commission external evidence reviews (a technology assessment or a MEDCAC meeting), including coverage with evidence development (CED) criteria (if applicable). As needed, CMS commissions external evidence reviews, which include technology assessments–systematic reviews of the evidence conducted by a third-party contractor–and convenes meetings of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)–to

supplement its research.[3] If needed, the agency may also develop CED study criteria, which is when a promising item or service is covered in a clinical study on the condition that more evidence is collected. According to the specified time frames, this step must be completed within nine months of initiating the review.

Step 10: Publish proposed decision memo, including CED criteria (if applicable). The proposed decision memo typically includes a detailed analysis of the evidence, rationale for the proposed decision, patient populations considered, details of study designs, and a summary of the decision. The proposed decision memo also addresses any potential concerns or limitations of the evidence, and may include CED study criteria. According to the specified time frames, CMS must publish the proposed decision memo to its website within six months after initiation for internal evidence reviews, or nine months if an external evidence review is needed.

Step 11: Hold 30-day public comment period. After the proposed decision is published, CMS opens a 30-day public comment period to solicit feedback from the community including stakeholders through its Medicare Coverage Database website. CMS reviews all public comments and publishes consolidated responses in the final decision memo.

Step 12: Publish final decision memo, including CED criteria (if applicable). CMS publishes its final decision memo after which claims for the item or service may be submitted on behalf of Medicare beneficiaries. CMS may decide to issue an NCD that could include coverage criteria, CED study criteria, non-coverage criteria, or a determination that a national coverage policy is not appropriate. In cases where CMS determines that no national policy is needed, the agency allows Medicare contractors to make claim-by-claim determinations for the item or service. CMS may also use CED. The final decision memo is published sixty days after the public comment period closes.

Step 13: Approve CED clinical study (if applicable). CMS may approve the CED clinical study and post the information on its website to

[3]CMS established MEDCAC to provide independent guidance and expert advice on health care topics, and NCD processes and requests. Technology assessments may include collecting and analyzing data, and evaluating the safety, effectiveness, and appropriateness of the item or service under analysis.

inform the public of the topics and studies underway. There is no explicit time frame for this step.

Step 14: Develop implementation instructions. Throughout the analysis process, CMS works with other Department of Health and Human Services groups and external entities to publish implementation instructions on the CMS website. These instructions reiterate the effective date of the NCD, specify changes to computer systems, including those for Medicare Administrative Contractor. There is no explicit time frame for this step.

Step 15: Review CED clinical study findings (if applicable). CMS reviews CED study findings and may decide to reconsider the NCD and adjust coverage if CMS determines that the evidence supports coverage of the item or service. There is no explicit time frame for this step.

Step 16: Reconsider or remove NCDs older than 10 years. CMS may reconsider an NCD through the NCD process at any time. However, CMS periodically conducts internal reviews of existing NCDs that are 10 years or older and may choose to reconsider or remove such NCDs There is no explicit time frame for this step.

Appendix III: Coverage Analyses Finalized from Fiscal Year 2013 Through February 2025

Table 3: Coverage Analyses Finalized from Fiscal Year 2013—February 2025

Coverage analysis title	Date of request letter	Initiation date	Final decision publication date
Positron Emission Tomography	3/30/2012	7/11/2012	3/7/2013
Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration	5/25/2012	7/24/2012	4/3/2013
Positron Emission Tomography for Solid Tumors	7/20/2012	9/12/2012	6/11/2013
Aprepitant for Chemotherapy-Induced Emesis	2/14/2012	10/1/2012	5/29/2013
Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease	6/29/2012	10/9/2012	9/27/2013
Cardiac Pacemakers	12/18/2012	1/24/2013	8/13/2013
Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement	1/18/2013	1/24/2013	9/24/2013
Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy	1/16/2013	2/7/2013	10/30/2013
Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis	Internal request	4/5/2013	1/9/2014
Cardiac Rehabilitation Programs - Chronic Heart Failure	3/26/2013	6/4/2013	2/18/2014
Intensive Cardiac Rehabilitation Program - Benson-Henry Institute Cardiac Wellness Program	3/20/2013	9/3/2013	5/6/2014
Screening for Hepatitis C Virus in Adults	Internal request	9/5/2013	6/2/2014
Transcatheter Mitral Valve Repair	11/14/2013	11/18/2013	8/7/2014
Screening for Lung Cancer with Low Dose Computed Tomography	10/25/2013	2/10/2014	2/5/2015
Microvolt T-wave Alternans	3/20/2014	4/23/2014	1/13/2015
Screening for the Human Immunodeficiency Virus (HIV) Infection	5/13/2014	8/4/2014	4/13/2015
Screening for Colorectal Cancer - Stool DNA Testing	5/6/2014	8/11/2014	10/9/2014
Screening for Cervical Cancer with Human Papillomavirus Testing	4/24/2014	11/25/2014	7/9/2015
Positron Emission Tomography to Identify Bone Metastasis of Cancer	2/5/2015	3/16/2015	12/15/2015
Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease)	1/23/2015	4/30/2015	1/27/2016
Percutaneous Left Atrial Appendage Closure	4/24/2015	5/21/2015	2/8/2016
Gender Dysphoria and Gender Reassignment Surgery	3/1/2014	12/3/2015	8/30/2016
Screening for Hepatitis B Virus Infection	5/28/2015	1/21/2016	9/28/2016
Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis	3/27/2016	4/13/2016	12/7/2016
Leadless Pacemakers	Internal request	5/18/2016	1/18/2017
Hyperbaric Oxygen Therapy	3/16/2015	7/12/2016	4/3/2017

Coverage analysis title	Date of request letter	Initiation date	Final decision publication date
Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease	9/13/2016	9/15/2016	5/25/2017
Implantable Cardioverter Defibrillators	Internal request	5/30/2017	2/15/2018
Magnetic Resonance Imaging	Internal request	7/12/2017	4/10/2018
Next Generation Sequencing for Medicare Beneficiaries with Advanced Cancer	11/17/2017	11/30/2017	3/16/2018
Chimeric Antigen Receptor T-cell Therapy for Cancers	2/22/2018	5/16/2018	8/7/2019
Vagus Nerve Stimulation for Treatment Resistant Depression	10/25/2017	5/30/2018	2/15/2019
Transcatheter Aortic Valve Replacement	10/25/2017	6/27/2018	6/21/2019
Ambulatory Blood Pressure Monitoring	5/18/2018	10/9/2018	7/2/2019
Acupuncture for Chronic Low Back Pain	Internal request	1/15/2019	1/21/2020
Next Generation Sequencing	Internal request	4/29/2019	1/27/2020
Transcatheter Mitral Valve Repair	4/29/2019	8/14/2019	1/19/2021
Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy	7/12/2019	2/3/2020	12/1/2020
Screening for Colorectal Cancer Blood-Based Biomarker Tests	4/12/2019	2/28/2020	1/19/2021
Autologous Blood-Derived Products for Chronic Non-Healing Wounds	5/9/2019	4/3/2020	4/13/2021
Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches	1/11/2019	8/17/2020	9/27/2021
AlloMap® Molecular Expression Testing for Detection of Rejection of Cardiac Allografts	1/22/2013	10/16/2020	4/13/2021
Transvenous (Catheter) Pulmonary Embolectomy	Internal request	4/13/2021	10/28/2021
Screening for Lung Cancer with Low Dose Computed Tomography	3/9/2021	5/18/2021	2/10/2022
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease	Internal request	7/12/2021	4/7/2022
Cochlear Implantation	10/27/2020	3/1/2022	9/26/2022
Home Use of Oxygen	Internal request	5/12/2022	7/8/2022
Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease	Internal request	6/16/2022	10/13/2023
Seat Elevation Equipment (Power Operated) on Power Wheelchairs	9/15/2020	8/15/2022	5/16/2023
Pre-Exposure Prophylaxis for Human Immunodeficiency Virus Prevention	2/1/2022	1/12/2023	9/30/2024
Percutaneous Transluminal Angioplasty of the Carotid Artery Concurrent with Stenting	6/2/2022	1/12/2023	10/11/2023
Allogeneic Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndromes	10/12/2021	6/7/2023	3/6/2024

Coverage analysis title	Date of request letter	Initiation date	Final decision publication date
Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management	11/3/2022	4/30/2024	1/13/2025

Grey = Grey rows indicate analyses that took longer than the specified time frames.

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-25-107623

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

September 2, 2025

Leslie V. Gordon
Director
Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Gordon:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"MEDICARE: National Coverage Determinations Are Generally Timely, but Improvements Are Needed"** (GAO-25-107623).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Gary Andres
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEDICARE: NATIONAL COVERAGE DETERMINATIONS ARE GENERALLY TIMELY, BUT IMPROVEMENTS ARE NEEDED (GAO-25-107623)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

Medicare payment is contingent on a determination that an item or service fits within a statutory benefit category, is not specifically excluded from coverage, and in most circumstances, that the item or service is "reasonable and necessary" for Medicare beneficiaries. Section 1862(a)(1)(A) of the Social Security Act (the Act) states that, subject to certain exceptions, no payment may be made for any expenses incurred for items or services that are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member…." CMS exercises its statutory authority to make coverage determinations regarding whether specific items or services fit within one of the broadly defined benefit categories and can be covered under the Medicare program.

The vast majority of coverage is determined on a local level and developed by clinicians at the contractors that pay Medicare claims.[1] However, in certain cases, Medicare deems it appropriate to develop a National Coverage Determination (NCD) for an item or service to be applied on a national basis for all Medicare beneficiaries meeting the criteria for coverage.

As defined in section 1862(*l*)(6)(A) of the Act, an NCD is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Act. In general, an NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a particular medical item or service. An NCD is usually written in terms of a specific patient population that may receive (or not receive) Medicare payment for a particular item or service. NCDs are binding on all Medicare Administrative Contractors, Administrative Law Judges, and the Medicare Appeals Council.

NCDs are made through an evidence-based process, with opportunities for public participation. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). NCDs are posted on the CMS Medicare Coverage Center website and provide stakeholders with the Medicare coverage criteria, a summary of the evidence considered, and CMS's rationale for the decision. If CMS has a large volume of NCD requests for simultaneous review, requests are prioritized based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.

The national coverage determination process described in section 1862(*l*) of the Act includes timeframes for decisions on requests for NCDs. GAO found that NCDs are generally timely but identified opportunities for improvement within the process.

GAO's recommendations and HHS's responses are below.

[1] Specifically, in the absence of a national coverage policy, coverage of an item or service is determined based on a local coverage determination (LCD), if applicable, or at the discretion of the Medicare contractors on a claim-by-claim basis.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEDICARE: NATIONAL COVERAGE DETERMINATIONS ARE GENERALLY TIMELY, BUT IMPROVEMENTS ARE NEEDED (GAO-25-107623)

GAO Recommendation
The Administrator of CMS should identify the causes of any delays in national coverage determinations and take actions, as appropriate, to better ensure that analyses are finalized within the specified time frames.

HHS Response
HHS concurs with this recommendation. HHS will take GAO's finding and recommendation into consideration as we explore opportunities to improve the coverage determination process.

GAO Recommendation
The Administrator of CMS should make available to the public the criteria it uses to prioritize its analyses of national coverage determination requests.

HHS Response
HHS concurs with this recommendation. HHS will take GAO's finding and recommendation into consideration as we determine appropriate next steps.

HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and other issues in the future.

Appendix V: GAO Contact and Staff Acknowledgements

GAO Contact

Leslie V. Gordon, GordonLV@gao.gov

Staff Acknowledgments

In addition to the contact named above, Jennel Lockley (Assistant Director), Ling Guo, and Alexis Hartranft made key contributions to this report. Also contributing were Sam Amrhein, Ariel Landa-Seiersen, Richard Lipinski, Jennifer Rudisill, and Ethiene Salgado-Rodriguez.

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