
Medicare Coverage Processes: An Analysis of Procedural and Resource Concerns

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Executive Summary

This report focuses on coverage for devices and issues related to procedural delays, the lack of transparency in Medicare's National Coverage Determination (NCD) process, the use of Coverage with Evidence Development (CED), harmonizing with the Food and Drug Administration (FDA), and ensuring patient safety. CMS has conducted its NCD review process for medical devices for many years but in recent years the process has slowed and become less predictable. The operational flaws that exist within the NCD process ultimately could prevent Medicare beneficiaries from accessing innovative technologies, especially at a time when CMS considers assuming new responsibilities for evaluating new technologies.

Medicare has broad authority to provide coverage for items and services that are determined to be reasonable and necessary for Medicare beneficiaries. Most Medicare coverage is determined at a local level using the statutorily mandated "reasonable and necessary standard." This means that coverage policy is developed by Medicare Administrative Contractors (MACs) that review and pay claims on behalf of Medicare. In many cases a specified, written coverage determination is not needed, and claims are adjudicated on a case-by-case basis. However, in some cases, Medicare will develop a National Coverage Determination (NCD), which specifies coverage of an item or procedure and outlines specific coverage parameters.

Medicare NCDs are widely influential, because they directly apply to the coverage of the 65 million Medicare beneficiaries enrolled in Traditional Medicare and Medicare Advantage (MA) plans, but also because Medicaid programs and commercial insurers often view NCDs as a baseline for establishing their own coverage policies.^{i,ii} Given the highly influential role the Medicare national coverage process plays in the health care landscape, manufacturers of innovative technologies view obtaining Medicare coverage as a critical step for broader marketplace reimbursement.ⁱⁱⁱ

Both federal statute and CMS regulations define the requirements of the NCD process. Statute requires that NCDs must be made through an evidence-based process with opportunities for public participation. Statute also requires that the Secretary of the US Department of Health and Human Service (HHS) assess whether items or services are "reasonable and necessary," and that a final decision memo must be issued that includes the decision to grant, limit, or exclude coverage, and that summarizes any public comments and includes responses. In addition, statute defines the timing of certain phases of the NCD process. CMS regulations define several aspects of the NCD process, including the timing of additional phases. Based on these statutory and regulatory requirements, the totality of CMS's NCD timeline includes six phases.

The Coverage and Analysis Group (CAG) within the Centers for Clinical Standards and Quality (CCSQ) is responsible for the daily work of developing and implementing NCDs, among other responsibilities. The manner in which CMS implements the statutory and regulatory requirements for the existing NCD process is critical to understand and potentially improve at this point in time as CMS considers moving forward with a new program that might provide Transitional Coverage for Emerging Technologies and result in additional responsibilities for CMS.

Our analysis of CMS data revealed that the number of NCD requests completing the NCD process decreased annually between 2003 and 2022 as the length of time required to complete the NCD review process increased. The potential inflection-point of these divergent trends was in 2014. In this year, the number of completed NCD requests continued to decline while the average duration of NCD requests began to increase. Between 2014 and 2022, the annual average duration of NCD requests was 483 days, a 56 percent increase above the 309-day average annual between 2003 and 2013.

The primary source of this change was an increase in the length of phases one and two of the NCD process. Between 2003 and 2013, phases one and two required an average of 52 days to complete. By contrast, between 2014 and 2022, phases one and two required an average of 228 days to complete.

This represents more than a 300 percent increase between the two time periods. Delays in phase three of the NCD process also are evident, but it is during the initial phases that the lags are most apparent.

CMS has demonstrated a commitment to ensuring beneficiaries have access to innovative medical technologies. Most recently, in June 2023 the agency released a new regulation proposing process modifications to enable emerging technologies to receive transitional coverage, the “Transitional Coverage for Emerging Technologies” Proposed Rule.^{iv} In this regulation CMS proposed to offer early NCD evidence reviews and to enable manufacturers to work with CMS to develop evidence plans. Nonetheless, correspondence from CMS to manufacturers also suggests that the agency may currently have resource constraints that cannot fully meet the demand for NCD requests. However, it is unclear what other factors may be causing CMS to believe their capacity to complete NCD reviews is limited.

Stakeholders including patients, manufacturers, provider trade associations, and thought leaders have identified a wide variety of concerns about CMS’s NCD process. Many support modifying the NCD process to make it more standardized, predictable, and transparent. Stakeholders have expressed concern about unnecessary delays in gaining Medicare coverage for innovative technologies. Others assert that the delays can lead to access inequities or impair patient safety. Some stakeholders suggest that reasons for the delays could include a lack of sufficient resources within the department at CMS which operates the NCD process.

Improving the operational aspects of the NCD process is important because this process plays a role in maintaining a robust Medicare program. The NCD process ensures that beneficiaries enrolled in Traditional Medicare and Medicare Advantage plans have access to innovative technologies, coverage is standardized nationally, and beneficiaries are receiving appropriate care. The consistency of the NCD process across Traditional Medicare and Medicare Advantage is particularly important as Medicare Advantage plans have grown rapidly in recent years. Further, this process is also an important mechanism for ensuring that the Medicare program is financially sound and covers services that deliver value to beneficiaries.

Based on the findings of our analysis we offer the following six recommendations to policymakers for improving CMS’s NCD process—through changes in Medicare statute or regulation or both. Five of these recommendations would require changes to law or regulation. The sixth recommendation would increase funding for CMS’s CAG. We also offer approaches CMS may take in order to enhance the agency’s internal staffing resources.

Recommendations and Approaches for Policymakers	
Recommendations requiring changes to law or regulation to improve the NCD process	
1	Define administrative timeframes for the initial phases of the NCD process.
2	Improve the transparency of the NCD process by publicly reporting the number of NCD requests of all types CMS receives, defining the prioritization criteria the agency uses to review these requests, and completing the Medicare Coverage Determination Report to Congress annually.
3	Define a process with administrative timelines and review criteria for revising and retiring NCDs.
4	Assign NCD applicants to a specific CMS staff person who can serve as their NCD process navigator and is available to work with applicants ahead of the formal request process.
5	Implement performance metrics to measure outcomes to assess the NCD process, such as the duration of application reviews and the rate at which finalized NCDs are revisited or terminated.
Recommendation for increasing funding for new internal processes	
6	Increase CMS’s program management budget for staffing resources devoted to the NCD process and new initiatives for coverage of emerging technologies.
	This recommendation may be accomplished through one of three approaches:

	<ul style="list-style-type: none"> • CMS reallocates its program management budget to increase funding for the NCD process. • Congress provides additional funding for CMS’s program management budget through the appropriations process, and a directive that CMS allocate some portion of the additional funding to the NCD process. • Congress specifically earmarks new discretionary funding for the CMS NCD process through the appropriations process.
Approaches CMS may use to enhance agency staffing resources	
A	“Borrow” physicians or other clinicians specializing in the areas of medicine or the areas of research that the NCD requests warrant from other parts of CMS or HHS.
B	Hire additional clinical and research experts as full time CMS employees from outside the agency. However, some have noted that CMS often cannot compete with Public Health Service (PHS) agencies for these experts because those agencies can better compensate these experts given their “Title 42 authority.”
C	Outsource NCD reviews to external consultants with the expertise needed for each review. CMS could accredit third-party contractors to conduct relevant research and analysis on specific types of NCDs to supplement CMS’s technical expertise and expand its capacity. This approach could follow the FDA’s existing program for 501k reviews, which are aimed at lower complexity reviews.
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Introduction

This report focuses on coverage for devices and issues related to procedural delays, the lack of transparency in Medicare's National Coverage Determination (NCD) process, the use of Coverage with Evidence Development (CED), harmonizing with the Food and Drug Administration (FDA), and ensuring patient safety. CMS has conducted its NCD review process for medical devices for many years but in recent years the process has slowed and become less predictable. The operational flaws that exist within the NCD process ultimately could prevent Medicare beneficiaries from accessing innovative technologies, especially at a time when CMS considers assuming new responsibilities for evaluating new technologies.

The Centers for Medicare & Medicaid Services (CMS) establishes national coverage policy for Medicare Part B medical devices, drugs, biologics, and other Medicare inpatient and outpatient services through the National Coverage Determination (NCD) process. The Social Security Act outlines the various requirements of the Medicare program including indicating that Medicare will pay for items and services that are deemed "reasonable and necessary for the diagnosis or treatment of an illness or injury" (within the scope of Medicare benefits). In administering the Medicare program, CMS has established processes for determining the "reasonable and necessary" standard for specific items and services including innovative medical device technologies. Medicare's reasonable and necessary standard for coverage differs from the U.S. Food and Drug Administration's (FDA) statutory requirement to base approval decisions on whether an item is "safe and effective", and for medical devices specifically based on whether there is "reasonable assurance" of safety under the Federal Food, Drug, and Cosmetic Act.

Medicare uses both national and local processes to determine Medicare coverage. This paper focuses on issues associated with NCDs and specifically those related to coverage of devices. CMS can initiate an NCD or a member of the public, such as a Medicare beneficiary, provider, or manufacturer, may request an NCD for a specific item or service. In reviewing NCD requests, CMS evaluates the evidence available to support the specific request and then allows opportunities for public comment on the agency's draft decision and its supporting evidence. CMS also has a Federal Advisory Committee, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), available for outside consultation and technology assessment when additional review is needed. In the absence of a national policy, local Medicare contractors have discretion to make coverage decisions that apply in their jurisdiction.^v

CMS's Medicare coverage decisions apply to all 65 million beneficiaries regardless of whether they are enrolled in Traditional Medicare or a Medicare Advantage plan. In addition, other payers including Medicaid programs and commercial insurers often either defer to or use Medicare coverage policy as a baseline for establishing their own coverage policies.^{vi,vii} Given the highly influential role the Medicare coverage process plays in the health care landscape, manufacturers of innovative technologies view obtaining Medicare coverage as a critical step toward ensuring broader marketplace reimbursement.^{viii}

Congress has modified the requirements for the NCD process at several points in time and CMS has also made regulatory updates to reflect the changing program and technological and medical advancements over the past decades. In recent years, however, the NCD process appears to be lagging behind the demand for more NCDs to support technological innovation. CMS leadership is aware of this situation and is considering approaches to modifying the NCD process. In 2022, CMS stated in correspondence to NCD applicants that it was pausing certain NCD reviews due to the agency's internal capacity restraints. In addition, in June 2023 the agency released a new regulation proposing process modifications to enable emerging technologies to receive transitional coverage, the "Transitional Coverage for Emerging Technologies" Proposed Rule.^{ix} In this regulation, CMS proposed to offer early NCD evidence reviews and to enable manufacturers to work with CMS to develop evidence plans.

Stakeholders and thought leaders have expressed wide-ranging concerns about the complex NCD process. For many years, stakeholders have asked for more transparency regarding how and when CMS will initiate an NCD. In addition, as the volume of completed NCDs has decreased in recent years, some

stakeholders have questioned whether CMS has the resources it needs to review the volume of complex NCD requests it receives. Some stakeholders also have expressed concern about the process CMS uses to grant an NCD conditionally and in conjunction with the gathering of information, referred to as an NCD requiring Coverage with Evidence Development (CED). Though concerns about the added burden of CED and the methods used to conduct CED are important, this paper focuses on the procedural aspects of the review process that affect all NCDs.

The Advanced Medical Technology Association (AdvaMed) commissioned Health Management Associates (HMA) to assess the operational aspects of the NCD process and to offer recommendations on how this could be improved. HMA's conducted its analysis independent of AdvaMed from January to May 2023. HMA's research methodology included the following steps which are described more fully in Appendix 1

- Assess CMS's statutory and regulatory documentation to map and describe the NCD process.
- Conduct an analysis of the Medicare Coverage Database and the NCD requests being reviewed.
- Gather stakeholders concerns about the NCD process through interviews and a literature review.
- Assess FDA's approval processes for medical devices, and how user fees fund these processes.

Medicare Statutory and Regulatory Requirements for the Coverage of New Medical Devices and Emerging Technologies

Overview of Statutes and Regulations Related to the Medicare Coverage Process

CMS's process for making coverage decisions is defined both in statute and agency regulation (See Appendix 2 for detail). Although the Social Security Act holds the HHS Secretary responsible for Medicare coverage decisions, the authority to conduct this work has been delegated to the CMS. In particular, the Coverage and Analysis Group (CAG) within the Centers for Clinical Standards and Quality (CCSQ) is responsible for the daily work of developing and implementing NCDs.^x This group consists of physicians and other clinicians, policy analysts and researchers dedicated to overseeing the Medicare coverage process. Ultimately, all of the CAG and CMS work is done under the authority in the law that has been delegated down from the Secretary.

Based on these statutory and regulatory requirements CMS's NCD timeline spans six phases. For coverage decisions that include a device, generally, it must first have received authorization from the FDA. After that, a stakeholder may submit a request to CMS's CAG and the process follows six phases that are defined either by statute or regulation. Below we define each of the six phases and in Figure 1 highlight phases one, two, and six, because these phases are areas of concern and the subject of some of our recommendations.

Phase 1: The time between when the stakeholder submits the NCD request and when CMS's CAG accepts the request.

Phase 2: The period between when the CAG accepts the request and when the CAG formally initiates the evidence review of the medical device.

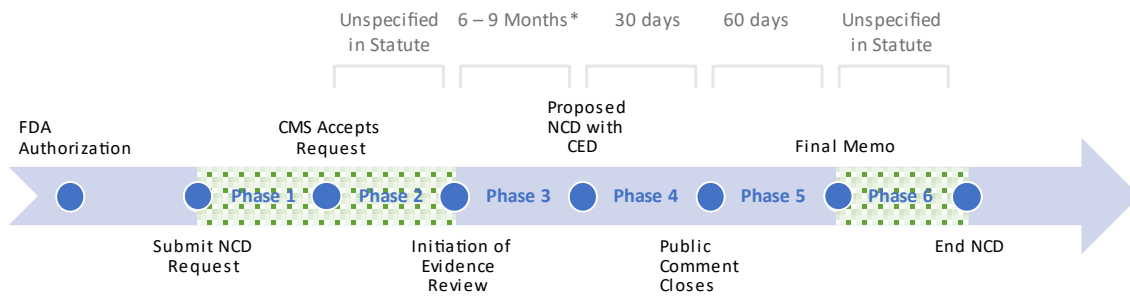
Phase 3: The statutorily defined six-to-nine month period between when CMS's evidence review begins and when CMS must release the draft NCD memo to the public, including 30-day public comment period, defined through regulation, when the NCD review is announced to the public.

Phase 4: The statutorily defined 30-day period between when CMS must post the proposed NCD decision memo for each application and the end of the public comment period.

Phase 5: The statutorily defined 60-day period CMS is allotted between when the public comment period ends and CMS must release the final NCD decision memo for each application.

Phase 6: The period between an NCD becomes effective and the NCD is terminated.

Figure 1: National Coverage Determination Process, and phases of concern



* Contains a 30-day Public Comment Period once CMS initiates evidence review.

In addition, for several years CMS has used CED as part of the NCD process in order to accelerate access to medical devices and other services that the agency has determined, based on the available evidence are reasonable and necessary for Medicare beneficiaries. That evidence has often been gathered through the FDA approval process.^{xi,xii} Importantly, FDA standards for approval differ from CMS standards for coverage, and it is not unusual for CMS and FDA evidence to be misaligned given their differing purposes. As a part of granting an NCD with CED, CMS effectively covers devices or services as long as certain conditions are met, such as the provider gathering patient outcome data through a patient registry or the service being limited to certain providers or patient populations. Further, the agency agrees to cover these items and services through an NCD until enough evidence is available to update the NCD and expand, limit, or revoke coverage.^{xiii} According to CMS guidance, a CED cycle is considered complete when the requirement for study participation as a condition of coverage is removed.^{xiv,xv}

In the absence of NCD, Medicare’s local contractors (Medicare Administrative Contractors or MACs) have the authority to determine coverage for items and services on a claim-by-claim basis or to establish local coverage determinations (LCDs) following the same reasonable and necessary statutory requirements. MACs consider complete, formal requests from beneficiaries, health care professionals, and any interested party in their jurisdiction for items and services that do not have a NCD, or when there is no need for a NCD^{xvi}. This report will primarily focus on the coverage process, experience, and potential solutions related to national coverage, rather than LCDs.

Number of NCD requests completing the review process has declined annually and the length of time requests spend under review has increased

The pool of NCD requests is diverse, and the scope of NCD requests not granted review by CAG or with delayed review is unclear

To assess the number of NCD requests being completed by CMS, and the length of time NCD requests spend in the NCD review process, HMA conducted an analysis of CMS's Medicare Coverage Database (MCD).

The pool of NCD requests fielded by CAG is diverse in subject and context, suggesting that the task of reviewing NCD requests must be done on an individual basis and with highly specialized expertise. Between 1999 and March 8, 2023, the MCD identified 246 National Coverage Analyses (NCAs) that the CAG initiated. Among these NCAs, 242 were completed cases, three were open cases, and one was open for public comment. NCD requests seeking coverage for the first time ("New NCD requests") accounted for 61 percent of the NCAs. NCD requests seeking revisions to existing NCDs ("Revision NCD requests") accounted for 39 percent of the NCAs.

Further, 56 percent were generated externally, meaning the application for the NCD request came from outside of CMS. By contrast, 43 percent of NCAs were internally generated, meaning these requests for coverage analysis originated from within CMS and certain information, like the request date and request letter, is not publicly available. Because of the limited data available for internal requests, we cannot provide descriptive information on all phases of the process for internal requests. Among the externally generated requests, new NCD requests accounted for 53 percent of cases, whereas new internal requests accounted for 72 percent of NCAs. A small share of completed NCD reviews have included CED. To date, CMS has granted 21 NCDs with CED, representing less than 9 percent of all NCAs. However, since the first CED was issued in 2007, the percentage of NCAs with CEDs is closer to 22 percent.

NCAs are distributed across an array of clinical subjects. The NCAs include items and services such as medical devices, durable medical equipment, drugs, biologics, or other services. Within the MCD, CMS identifies the primary benefit category of each NCA. Three primary benefit categories account for 54 percent of all NCAs: diagnostic tests (24 percent), inpatient hospital services (21 percent), and durable medical equipment (9 percent). Among the remaining 46 percent of NCAs, no single primary benefit category accounts for more than 9 percent of NCAs.

Importantly, data included in the MCD are limited to NCD requests for which the CAG has initiated an NCA review. Therefore, the MCD omits NCD requests that the CAG denied or are awaiting acceptance or initiation of evidence review from the CAG. Therefore, we are unable to provide counts or other descriptive information pertaining to the total number of NCD requests the CAG received overall. This gap in the data prevents HMA, and other interested parties from understanding the full scope of the CAG's workload.

Besides what is posted in the MCD, there is not much transparency from CMS regarding how they manage NCD requests, prioritize requests or keep track of requests that are in the queue for future review (the "waiting list"). CMS at one point did publish an NCD waitlist dashboard on its website but has not updated it since September 2020.^{xvii} The dashboard was a positive step for transparency, but it was incomplete. It did not provide complete details regarding the NCAs that were underway or the NCDs that had been finalized. It is not clear why CMS has not updated it since 2020.

Number of NCD requests completing the review process decreased annually as the length of reviews increased

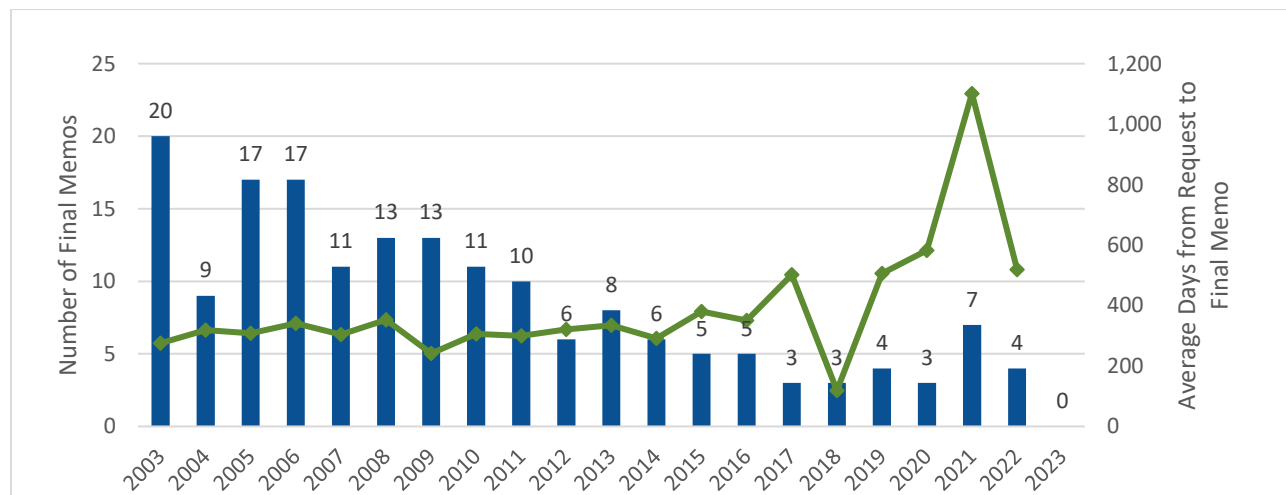
The number of final decision memorandums (FDMs) CMS issued decreased between 2003 and 2022, whereas the length of time required to complete FDMs increased. Figure 2 demonstrates the consistent decline in the number of FDMs generated by the NCD process annually. Given this downward trend, HMA observed that internal requests declined slightly more rapidly than external requests.^{xviii} However, FDMs involving both new and revision NCDs declined over this period consistent with the overall downward trajectory.

Beginning in 2014, longstanding trends in the length of time required to complete NCD reviews changed and began to lengthen. Using 2014 as an inflection point, we formed two general time periods to demonstrate the relationship between volume of FDMs and the length of time required to complete FDMs. Between 2003 and 2013, CMS generated slightly more than 12 FDMs annually, and between 2014 and 2022 the agency issued slightly more than nine FDMs per year (Figure 2). This represents a roughly 25 percent decrease in the number of annual FDMs over the course of these time spans.

By contrast, between 2003 and 2013, the average length of time between initial NCD request and the agency’s completion of the FDM was 309 days (about 10 months). Further, between 2014 and 2022 the average length of time between the initial NCD request and the FDM was 483 days (about 1 and a half years), which represents a 56 percent increase in the length of time to complete and NCD over the two periods.

Between 2003 and 2023, the number of both new and Revision NCD requests declined consistent with the overall trend described above.

Figure 2. Count of Final Coverage Determinations Memorandums and Average Length of Time Between Requests and Final Memorandums for External Requests, by Year (2003 - 2022)



Source: CMS Medicare Coverage Database, as of March 8, 2023

Delays have increased in early phases of the NCD process

To assess the source of delays in the NCD process we turned to data associated with external NCD requests because CMS reports dates for each phase of these external requests within the MCD. We observed an increase in the length of phases one and two, the combined time between the request submission and CMS initiating evidence review. Between 2003 and 2013, phases one and two required an average of 52 days (about 1 month 3 weeks) to complete (Table 1). By contrast, between 2014 and 2022, phases one and two required an average of 228 days (about 7 and a half months) to complete. This represents more than a 300 percent increase between the two time periods. Delays in phase three of the NCD process also are evident, but it is during the initial phases that the lags are most apparent.

Table 1. Average duration of NCD Process for external requests in days and percent change in duration across two periods from 2003 to 2022.

NCD Process Phase	Average annual duration (days)		Percent change in length of time
	2003-2013	2014-2022*	
Phase 1 and 2: NCD request submitted to CAG initiating review of the request	52	228	338%
Phase 3: CAG review of the NCD request to CAG release of the proposed NCD memorandum	158	184	16%
Phase 4 and 5: Release of the proposed NCD memorandum to CAG release of the final NCD memorandum	121	96	-21%**

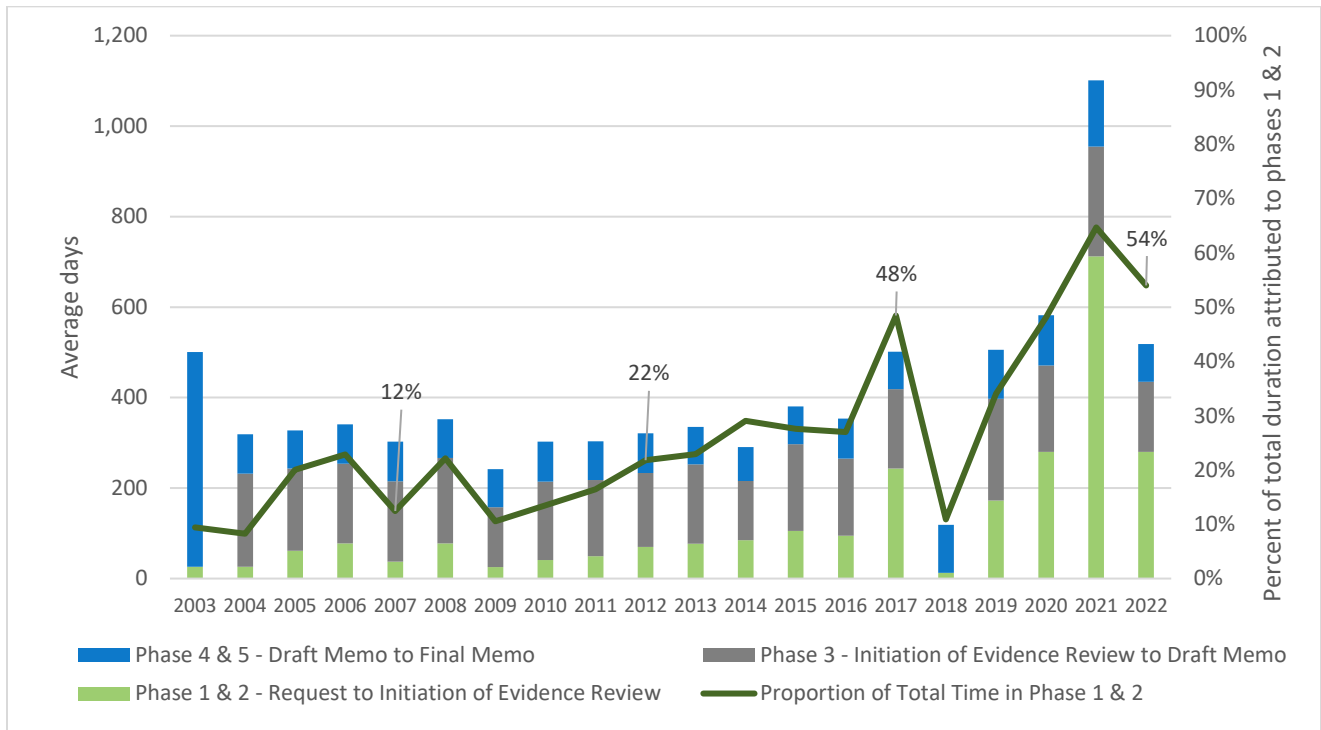
Source: CMS Medicare Coverage Database, as of March 8, 2023

* Data for 2018 are anomalous relative to all other years, for this reason 2018 data are excluded from these calculations. In 2018, only one external coverage request for next generation sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer was submitted and the proposed memo was posted within 13 days of the request.

** The percent change in length of time for phases four and five is negative largely because data for 2003 is an outlier because of missing data in the MCD. Had we used 2004, instead of 2003, as the base year, the percent change in length of time for phases four and five would have been positive +12 percent, or the average duration would have increased to 96 days (about 3 months) from 86 days (about 3 months) across the two periods.

Over the 20-year period, Figure 3 shows that phases one and two of the NCD process have increased as a share of the overall review duration between external request and release of the FDM. For example, in 2017 and 2022 phases one and two accounted for an average of 48 and 54 percent of the overall review duration respectively. By contrast, in 2007 and 2012 phases one and two accounted for an average of 12 percent and 22 percent of the overall review duration, respectively. Though these examples highlight individual years, they reflect the broader trends in the two periods used in this analysis.

Figure 3. Average days for Phases of the Medicare NCD Process by Year Contrasted with the Share of Total Days Attributed to Phases 1 and 2 (Limited to External Requests), 2003 - 2022



Source: CMS Medicare Coverage Database, as of March 8, 2023

On an individual case level, NCD reviews for several requests have been extremely long. Between 2014 and 2022, CMS required 200 or more days to advance 16 NCAs from the time of the initial external request to the initiation of evidence review (See Appendix 3). This time period combines Phases 1, 2 and 3. We combine these three periods, because the data reveal that following the release of the proposed decision memo CMS’s NCD process becomes more consistent as the agency adheres to statutory timelines. We also want to highlight that the evidence review of the NCD request for *AlloMap® Molecular Expression Testing For Detection of Rejection of Cardiac Allograft*, which was initiated in 2013, waited until 2020 for evidence review to begin (phase three), and FDM was released in 2021. Though this example is an anomaly, it also displays how some requests can endure years of being in limbo within the NCD process.

CMS Perspective on Covering Innovative Technologies

CMS expressed a commitment to preserving access to innovative technologies

CMS stated in 2021 that the agency is committed to ensuring people on Medicare have quicker access to innovative medical technologies for life-threatening or irreversibly debilitating diseases – like cancer and heart disease.^{xix} As a part of that in January 2021, CMS published the final rule “Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” based on direction from Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors (EO 13890).^{xx,xxi} This final rule was rescinded by the agency in 2021, but had it remained implemented it would have granted

Medicare coverage of FDA-approved breakthrough devices for up to four years once the device received or cleared market authorization.^{xxii} In addition, as part of MCIT, manufacturers were tasked with voluntarily developing evidence to show the benefits of the technology and would be required to initiate a coverage request (e.g., NCD or LCD) at the end of the four years. The regulation was rescinded due to concerns that the new coverage approval process not sufficiently protecting patients and that the evidence of clinical benefit used to approve and cover the new technologies lacked inclusion of the Medicare population.

In 2022, the Secretary of HHS tasked the Agency for Health Care Research and Quality (AHRQ) with reviewing the CED requirements. The AHRQ's report recommended revising the existing 13 requirements to add explicit expectations for the studies, an explanatory guide to accompany requirements, and five additional requirements. The MEDCAC is reviewing available information from a 2023 meeting and will advise CMS on potential revisions to CED policy to ensure "consistent, feasible, transparent and methodologically rigorous criteria."^{xxiii}

In a December 2022 article in the *Journal of the American Medical Association (JAMA)*, representatives of CMS leadership stated that CMS was developing a regulation to replace the MCIT, which would adhere to four principles:^{xxiv}

- Manufacturers may enter the process on a voluntary basis. The process will be limited to medical devices that can be covered by Medicare because they fall within the program's existing benefit categories.
- CMS may conduct an early evidence review (before the device secures FDA marketing authorization) and discuss with the manufacturers the best Medicare coverage pathway, depending on the strength of the evidence collected.
- At the manufacturer's request, CMS may initiate the coverage review process before FDA market authorization, which could require developing an additional evidence development plan and confirming appropriate safeguards and protections for Medicare beneficiaries.
- If CMS determines that further evidence development is the best coverage pathway, the agency will explore how to reduce the burden on manufacturers, clinicians, and patients while maintaining rigorous evidence requirements.

Most recently, in June 2023 CMS released the "Transitional Coverage for Emerging Technologies" (TCET) notice, which proposed coverage policy changes consistent with the concepts discussed in the 2022 JAMA article.^{xxv} Within the TCET notice, CMS creates a pathway to temporary Medicare coverage that would be available for certain devices designated by the Food and Drug Administration (FDA) as "breakthrough devices." The new TCET process would precede the existing NCD process. The new process offers manufacturers early NCD evidence reviews and enables them to work with CMS staff to develop an evidence development plan (EDP) that will be used to generate the evidence CMS will need to make coverage decisions. Manufacturers would self-nominate their devices for TCET approval. Overall, the TCET process would involve three phases: 1) the 'pre-market' phase where the EDP is developed, 2) the 'coverage under TCET' phase where the device would be temporarily covered and the duration of temporary coverage would be determined by CMS depending on the evidence collection needs of the device, and 3) the 'transition to post-TCET coverage' phase involving evidence review and ultimately a CMS decision about whether the device receives an NCD (or not), an NCD with CED, or coverage with MAC discretion. In addition to the TCET notice, CMS released three corresponding guidance documents discussing the CED process, CMS's evidence review criteria, and knee osteoarthritis specifically.^{xxvi,xxvii,xxviii}

Collectively, CMS's TCET notice and guidance documents offer some additional transparency for stakeholders and applicants into the coverage process in general. In addition, the new process may

create a smoother glidepath for devices into the existing NCD process. However, CMS acknowledged in their TCET notice that the availability of the new TCET process may be limited.

CMS leadership suggests that their available resources for reviewing NCD requests may be insufficient.

The quantitative data shown in this report demonstrates the declining number of NCDs over the past 20 years and the increasing duration of NCD review completion. Reasons for this NCD process slowdown could include: an influx of NCD review requests that are not included the data CMS releases to the public through their MCD, CMS prioritizing other efforts within the agency above the NCD process, and/or a lack of resources within CAG to complete its work.

CMS correspondence with manufacturers suggests that the agency may have its own concerns about its capacity to complete all the NCD requests the agency receives. However, our ability to see the full extent of CMS's capacity limitations is limited. Specifically, CMS data prevent us from knowing the scope of requests that they turn away for review. In 2022, CMS sent at least two letters to NCA requestors stating that the agency must postpone action on individual requests they have accepted for review due to the agency's "internal capacity restraints." In both letters CMS noted that, consistent with an August 2013 Federal Register Notice (78 FR 48164-69) their prioritization strategy in the event of a large volume of NCD requests would be to "prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources."^{xxix} The receipt of these letters troubled the applicants and other stakeholders because CMS was effectively limiting a pathway available to manufacturers to ensure that Medicare beneficiaries have access to innovative technologies, especially when new clinical evidence has indicated that coverage restrictions defined in NCDs could no longer be justified.

CMS administrative budget for CAG is unclear to the public.

In FY2023, Congress appropriated \$4.125 billion to fund CMS's discretionary Program Management budget.^{xxx} The Program Management budget covers agency operations. Certain task such as Medicare Contractor Operations and Medicare Appeals have their own accounts in the budget and CMS reports on how much is spent in those areas. CAG staff and spending on conducting the NCD process is not separately reported and generally can be expected to come out of the Federal Administration account which covers the costs of CMS staff. CMS is concerned that its Program Management budget is insufficient and is requesting additional appropriations to support its work. In the FY 2024 "Budget in Brief" CMS said

"Program Management's enacted funding has not kept pace with the growth in enrollments, responsibilities and complexity within Medicare and Medicaid, putting both beneficiaries and taxpayers at risk. A substantial funding increase is needed to meet fundamental responsibilities, strengthen nursing home oversight, reduce prescription drug prices, advance health equity, enhance cybersecurity protections, improve quality, and conduct eligibility determinations as the public health emergency winds down."^{xxxi}

Growth of the Medicare Advantage program increases the importance of transparency and process improvements of the NCD process.

The growth of the Medicare Advantage program in recent years offers an additional reason why the NCD process must be more transparent and improved. MA plans are required to adhere to Medicare NCDs and LCDs, just as Traditional Medicare must adhere to these coverage determinations. In recent years,

the MA program has grown in terms of the number of beneficiaries enrolled in plans and the number of plans offering insurance to beneficiaries. In 2023, the Medicare Payment Advisory Commission (MedPAC) reported that from 2021 to 2022 the MA program grew by more than 2 million beneficiaries, bringing the share of all beneficiaries enrolled in MA plans up to 49 percent, from 46 percent. Further, MedPAC reported that in 2023 the average Medicare beneficiaries had access to 41 different MA plans, up from 36 MA plans in 2022.^{xxxii} Each plan has certain flexibility to administer medical benefits and often take advantage of the opportunity to implement prior authorization, step therapies, and other utilization management tools to limit costs. However, those tools cannot be applied to areas where there are existing NCD or LCDs.

Due to confusion amongst plans on how to implement coverage decisions, in 2022 and 2023 CMS clarified that NCDs and LCDs apply to MA plans, and underscored the importance of plans applying these coverage rules. First in March 2022, in a letter to the HHS Office of the Inspector General the CMS Administrator, Chiquita Brooks-LaSure stated:

Medicare Advantage Organizations (MAO) must follow national and local Medicare coverage determinations (NCDs and LCDs) and coverage guidance specified in original Medicare manuals, if specific guidelines exist for a given service. However, in many cases, NCD or LCD requirements are broad enough that an MAO may implement additional coverage requirements to better define the need for the service, as long as these additional requirements do not violate the requirements of the applicable NCD or LCD. Where there are no applicable NCDs or LCDs, MAOs may establish coverage guidelines, as long as the MAOs' guidelines are supported by medical evidence. Additionally, for services that are not subject to existing LCD and NCD requirements, MAOs may apply third-party guidelines, such as guidelines used by contractors engaged by the MAO to make coverage determinations.^{xxxiii}

Second, within the 2024 Medicare Advantage and Part D rule, CMS made a point of reinforcing for plans that MA plans are required to follow NCDs and LCDs and general coverage and benefit conditions included in Medicare law.^{xxxiv} This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. CMS also states that if there is not clear and fully established coverage criteria, MA plans may create their own coverage criteria but it must be publicly accessible and “based on current evidence in widely used treatment guidelines or clinical literature.”

Commenters to the proposed Medicare Advantage rule generally were not opposed to the requirement for MA plans to follow NCDs and LCDs, but some expressed concern that certain Medicare NCDs and LCDs could be out-of-date and encouraged CMS to ensure that the coverage policies are truly reflecting the most recent medical or scientific evidence and literature. CMS responded they believed that since their process utilizes expert consultation and public review and comment to stay up to date with current medical standards their process is sufficient when creating coverage guidelines. In addition, we anticipate that smaller or newer MA plans may begin to request NCDs and LCDs for items and services where coverage policy is unclear or undeveloped. It may be more efficient for them than establishing their own coverage criteria, especially for controversial or high-cost services.

Based on these comments, we anticipate that plans may become more active in the NCD and LCD processes to ensure the coverage policies are consistent with their preferences and commercial policies. If CMS does not have the resources to respond, plans may get frustrated and look to seek relief from the NCD policy requirements. However, to date plans have not been active requestors of NCDs.

CMS can look to the FDA approval for medical devices as an example for an efficient and more transparent process.

FDA Approval Process for Medical Devices

Before a medical device can be sold in the United States, it must be registered and cleared or approved by the FDA. There are two main pathways that manufacturers can use to bring their devices to market. The Pre-Market Approval (PMA) approval pathway involves conducting clinical trials to determine the safety and efficacy of the medical device and is generally used for novel and high-risk devices. The “510k pathway” is generally used for low- to moderate-risk devices and involves the manufacturer submitting evidence, including clinical evidence, to FDA to illustrate that the device is substantially equivalent to a device already on the market.^{xxxv} In 2022, consistent with other recent years, the FDA accepted 43 PMAs and 3,457 510ks.^{xxxvi}

The PMA and 510k pathways have specifically defined timelines. Under the PMA process, the FDA notifies applicants whether their application has been officially filed within 45 days of the agency receiving the application. Then the FDA has 180 FDA days to complete its review and issue either an order of approval or non-approval. Under the 510k process, the FDA notifies the applicant whether the notification has been officially accepted for review within 15 days of the agency receiving the application. Then the FDA has 90 FDA days to complete its review and issue a finding of substantially equivalent (SE) or not substantially equivalent (NSE).^{xxxvii} In practice, there may be multiple rounds of requests for data and conversations between the applicant and the FDA that could extend these timelines although the FDA would have still technically met their statutory obligations. In addition, the demands of the COVID-19 Public Health Emergency also distorted some of the usual order of FDA approvals.

FDA Medical Device User Fees

The FDA relies on payments made by manufacturers, referred to as user fees, to support the costs of the agency’s medical device approval/clearance processes. The Medical Device User Fee and Modernization Act (MDUFA), enacted in October 2002 authorized the collection of user fees to expedite the review of medical devices by the FDA and to make improvements in the regulation of medical devices. As a part of MDUFA, manufacturers must pay a user fee to the FDA for each submission that is submitted to the FDA for premarket review, but the Federal Food, Drug, and Cosmetic Act (FFDCA) only requires premarket review for moderate and high-risk devices.^{xxxviii} Since its initial approval, MDUFA has been reauthorized four times. The current version, MDUFA V, was implemented in 2022 and each version has been the result of an agreement between the device industry and the FDA and the enacted by Congress. Over the course of the five MDUFA agreements, industry and government have worked together to refine the process and modify requirements to add efficiency, capacity and stable infrastructure to the approval process. The FDA has been able to build an administrative infrastructure and robust team of experts to support the complexity and volume of the applications. The MDUFA refinements have also formalized a pre-submission review path. There is no fee associated with this process. It is an opportunity for manufacturers to request feedback from the FDA about a device they are considering submitting for approval. The FDA will review the submitted materials and respond in writing. This process can help guide a manufacturer to determine the best path to pursue for FDA submission and it may raise potential areas of concern in the approval process.^{xxxix}

Given the refinements that have occurred to the device approval process over the past 20 years, CMS could look to the FDA to seek improvements to the NCD process especially in terms of a stronger administrative infrastructure including more technical experts to support the demand for NCDs. CMS currently will work with the public ahead of an NCD submission, but the FDA’s pre-submission process illustrates an opportunity to more formalize that process. The FDA improvements have been funded by

user fees. User fees may not be appropriate for Medicare given the multiple ways to gain coverage and the limited number of NCDs requests per year. However, additional appropriated resources to CMS could improve transparency and infrastructure to support NCD requests.

Stakeholders cite procedural delays, lack of transparency, and unpredictability among concerns with the NCD process.

Stakeholders including manufacturers, provider trade associations, and thought leaders have identified a variety of concerns about CMS's NCD process with an emphasis on procedural delays, the lack of transparency, the use of CED, and patient safety. Based on our interviews, literature review, and analysis of stakeholder comments on the 2020 MCIT rule, it is evident that manufacturers are the most actively engaged stakeholders and have a range of perspectives that vary by size of the company. Manufacturers in general assert that the current NCD process restricts access to innovative technology due to being slow. Manufacturers support a standardized, transparent NCD process that is predictable, and seek improvements to the CED process. Hospitals, physician societies, and patient advocates generally are less engaged in this debate but have expressed concerns about a slow NCD process limiting access to innovative technologies and patient safety being threatened by a CED and patient access to innovative technologies.^{xl,xli,xlii,xliii,xliv,xlv,xlvi,xlvii,xlviii}

Below we summarize the most common concerns and suggestions we gathered from stakeholders.

- The NCD process is slow, unpredictable, and there is wide variation in how requests travel through the process.
- The NCD process is not transparent with regard to its timelines for when submitted requests are accepted or denied and how reviews are prioritized.
- CMS is not transparent about how it conducts re-evaluations of existing NCDs that may be outdated and inconsistent with medical practice.
- Given the projected growth in Medicare program enrollment and the fact that MA plans and other payers look to Medicare's NCDs and LCDs for baseline or precedent, it is critical that CMS keep NCDs and LCDs from becoming outdated.
- Flaws in the NCD process restrict access to innovative technologies for Medicare beneficiaries.
- CMS's NCD process and FDA's approval processes should be harmonized to create research efficiencies.
- The CED process is burdensome and expensive for manufacturers and providers, and the standards of evidence CMS requires are unclear.
- CMS lacks sufficient clinical and research expertise capacity to meet demand for the NCD reviews.
- Some manufacturers have resorted to the use of LCD, rather than endure the NCD process.
- CMS requires an increase in funding to support an overburdened NCD process.
- Provide CMS with alternative authorities needed to attract the clinical and research experts required to conduct NCD reviews.

Recommendations and Approaches for Policymakers

CMS has conducted its NCD review process for many years but in recent years the process has slowed and become less predictable. The operational flaws that exist within the NCD process may ultimately prevent Medicare beneficiaries from accessing innovative technologies. Improving the operational aspects of the NCD process is important because it plays a role in maintaining a robust Medicare program. The NCD process is intended to ensure beneficiaries have reasonable and necessary access to innovative technologies, that coverage is standardized nationally, and that beneficiaries receive appropriate care. This process also is an important mechanism for ensuring that the Medicare program is financially sound and covers services that deliver value to beneficiaries.

Based on the findings of our analysis we offer the following six recommendations to policymakers for improving CMS's NCD process—through changes in Medicare statute or regulation or both. Five of these recommendations would require changes to law or regulation. The sixth recommendation would increase funding for CMS's CAG. We also offer approaches CMS may take in order to enhance the agency's internal staffing resources.

Recommendations requiring a change to law or regulation to improve the NCD process

Recommendation 1: Define administrative timeframes for the initial phases of the NCD process.

Several stakeholders have expressed concern in recent years that CMS's NCD process has become delayed and that it can take years to complete. Over the last two decades the average length of time from initial request to CMS's initiation of evidence review has increased 300 percent. These first two phases of the NCD process (Figure 4) have been most delayed relative to the other phases. For example, for NCD reviews finalized by CMS in 2022, the average time spent on phases 1 and 2 was 280 days (about 9 months). While the other phases of the NCD process are linked to statutory or regulatory time frames, the first two phases of the process do not have time frames specified by statute or regulation. The extended length of time between the external request and initiation of evidence review indicates that the process is not working as outlined in statute, and leaves uncertainty for requestors.

Congress or CMS could adopt a similar strategy and establish a timeline for CMS to adhere to in the early phases of the NCD process. This may help applicants avoid the state of limbo that has entered into the process. By comparison, the FDA notifies applicants within 45 days when they are seeking medical device approval through the PMA process that their application has been officially filed. Specifically, Congress could revise sections 1862(l)(2)(A) and 1862(l)(2)(B) of the Social Security Act to include a time frame for NCD requests to be accepted or rejected by CMS. Congress could also specify that CMS must notify the requestor if 1) the initial review or the initiation of evidence review was not completed within the specified time frame and 2) provide a new time frame for when the applicable steps will be completed. CMS should include their compliance with these goals in the annual Medicare Coverage Determination Report to Congress.

Recommendation 2: Improve the transparency of the NCD process by publicly reporting the number of NCD requests of all types CMS receives, defining the prioritization criteria the agency uses to review these requests, and completing the Medicare Coverage Determination Report to Congress annually.

Improved transparency of the NCD process will yield greater standardization, predictability, and insight into how the process can be improved. Specifically, we identified three pieces of the NCD process that should be made more transparent. First, CMS needs to report the total number of applications it receives each year inclusive of the unaccepted requests and internally generated requests. Second, CMS needs to better clarify for the public how the agency will prioritize its docket of NCD requests. Third, CMS needs to commit to completing and releasing on a timely basis its annual Medicare Coverage Determination Report to Congress.

CMS does not report within the Medicare Coverage Database (MCD) or elsewhere the number of NCD requests it receives that the agency does not accept. CMS also does not make the same level of information available about internally generated NCD requests as external requests. Without this information, we cannot know how these cases increase administrative challenges and consume agency resources. To better understand the full extent of CMS's challenges related to the NCD process, the agency needs to begin including this information in the MCD. Making these changes will enable stakeholders and future NCD requesters to see what requests have been submitted, accepted, and rejected, and will then enable stakeholder to improve the quality of their NCD requests. Without further visibility into the volume of total requests and resource allocation within CMS, it is difficult to determine if increasing resources will reduce delays.

The criteria used by CMS to prioritize NCD requests is unclear despite the statement made by the agency in an August 2013 Federal Register Notice (78 FR 48164-69) stating that their prioritization strategy in the event of a large volume of NCD requests would be to "prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources." This statement provides the agency with enormous flexibility to select NCD requests, but stakeholders would prefer a more defined set of criteria. For example, the agency might consider prioritization criteria based on areas of clinical specialty, the size of the patient population impacted by the NCD, whether the NCD is a new versus revision request, or the date the NCD was received. Improved transparency in the prioritization criteria would assist stakeholders in planning their NCD requests and planning their investments.

With regard to the concerns expressed above about transparency, it is important to note that in September 2020, CMS posted on its website a dashboard (<https://www.cms.gov/files/document/ncd-wait-list.pdf>) listing the status of various NCD requests that had been received within the previous 12 months. This dashboard identified NCD requests under review at CAG, requests that had been reviewed but not yet opened (referred to as the NCD Wait List), requests that had been opened with a national coverage analysis (NCA) underway, and requests finalized. While the dashboard often failed to provide complete information about individual requests, it enabled stakeholders to confirm the status of requests and provided transparency and predictability to the process. CMS has not updated the dashboard since September 2020, but the agency should continue to maintain the NCD Waitlist dashboard, at least annually.

In addition, CMS should commit to submitting its Medicare Coverage Determination Report to Congress in 2023. CMS has not produced this report since 2021, and the consequence of not doing so in 2022 and 2023 (to date) is that Congress, stakeholders, and the public are uninformed about the status of the NCD process.^{xlix} This report allows each of these groups to better understand how the NCD process works, and what challenges the agency faces in completing its work.

Recommendation 3: Define a process with administrative timelines and review criteria for revising and retiring NCDs.

A predictable and standardized process for retiring NCDs and reevaluating NCDs would benefit all stakeholders. Phase 6 of the NCD process (Figure 4), is the time period after which CMS issues its final decision memo. This time period is currently open-ended and this is a concern. We assert that making this phase of the NCD process predictable and standardized may be critically important in the years ahead because the agency has recently instructed Medicare Advantage plans to rely upon NCDs and LCDs for defining coverage. Outdated NCDs could confuse or obstruct plan benefit or coverage decisions.

We applaud CMS for their efforts in recent years to remove outdated NCDs, but we believe CMS's review process should be standardized and made on a consistent basis. However, we believe the current process for reviewing and retiring NCDs is not clearly defined and could be strengthened. In addition, the agency does not currently have review criteria in place for reviewing existing NCD for potential revision. Because clinical practice standards change and innovative new products are entering the marketplace at a fast pace, we believe CMS should implement predictable timelines and clear review criteria for reviewing existing NCDs for revision and retirement. For example, the agency might consider reviewing all existing NCDs individually once every 5 years and the agency could clearly define a set of criteria it uses to arrive at a decision to retire the NCD or revise the NCD. These types of periodic reviews are common in other parts of the FFS reimbursement system for payment. In addition, a revised process such as this may reduce the number of NCD revision requests it receives annually. If at the end of an NCD's lifespan CMS has concerns about the use of the service ongoing, the agency could refer the service in question to the agency's oversight department. This may be particularly helpful when NCDs with CED are retired.

Recommendation 4: Assign NCD applicants to a specific CMS staff person who can serve as their NCD process navigator.

To address the various transparency and timing concerns expressed by NCD stakeholders, CMS could initiate a program which assigns a specific CMS staff navigator (or ombudsman) to each NCD requester. The navigator would serve as a regular point of contact for the NCD requester, clarify requesters' questions about the NCD process, and assist them in gathering evidence CAG requires for their given NCD request. The navigator could provide technical assistance about coverage and related coding issues and could be assigned to the requester early in the NCD process or even prior to submission of the NCD request.

Precedent exists at CMS for the navigator role described above, and we are suggesting that CMS build up from the foundation it has already created to offer more specific assistance to each NCD requester. Established by section 4010 of the 21st Century Cures Act, the Medicare Pharmaceutical and Technology Ombudsman is assigned to help support customer service and innovation in the Medicare program. This Ombudsman receives and investigates concerns and questions from pharmaceutical, biotechnology, medical device, diagnostic product manufacturers and other stakeholders regarding Medicare coverage, coding, and payment for products already covered or for which coverage is being sought. However, the navigator we are recommending differs from CMS's current Ombudsman. While the Ombudsman serves all NCD requests as needed, a navigator would specifically be assigned to each NCD request. We believe this is a more proactive approach for CMS.

Recommendation 5: Implement performance metrics to measure outcomes to assess the NCD process, such as the duration of application reviews and the rate at which finalized NCDs are revisited or terminated.

In order to enhance CMS's ability to maintain, monitor, and improve the NCD process it is critical that the agency implement metrics that offer information on the status of NCD's completed or under review. Using these data policymakers could evaluate how the NCD process is functioning and how it has changed after changes are made to the NCD process or new funding has been allocated to the NCD process.

A measurement process such as this exists within the FDA's medical device approval process, and it is reasonable to assume CMS could implement something similar.

CMS could identify several performance metrics that would assist the public and policymakers with identifying the resource needs of the NCD process. At a minimum, CMS should monitor the duration of time it takes for NCD requests to travel through the NCD process and the variance of this metric by clinical area and benefit category. In addition, CMS should create metrics which track the frequency with which existing NCDs are re-assessed and those that are retired.

The performance metrics CMS implements should be publicly reported on CMS's website to enable the public to understand the capacity limitations of the agency and its resource needs. These metrics could also be used to enhance the effectiveness of the annual Medicare Coverage Determination Report to Congress.

Recommendation for increasing funding for new processes

Recommendation 6: Increase CMS's program management budget for staffing resources devoted to the NCD process and new initiatives for coverage of emerging technologies.

Our analysis and review of CMS documents led to our conclusion that CMS's CAG requires additional resources in order to increase the rate at which the agency completes NCD reviews. Two letters sent by CMS to NCD applicants in 2022 stated that the agency, despite accepting the applicants' requests for reviews, must postpone action on individual NCD requests due to the agency's "internal capacity restraints." In addition, several stakeholders we interviewed identified a lack of resources within the CAG as a potential cause for delays in the NCD process. Further, our analysis of data from the NCD process confirms that the number of final decision memorandums completed by CMS has declined annually in recent years and corresponded with increase in the average length of time taken to complete those final decision memorandums. Finally, the CAG may soon be tasked with additional responsibilities, based on the proposed creation of CMS's new TCET process. The TCET process, as proposed, involves agency staff conducting evidence reviews prior to FDA approval and assisting manufacturers with developing evidence development plans. The three phases of the proposed TCET process will require significant resources to administer. While these phases may reduce some of the administrative burden associated with the NCD process, taken together the TCET and NCD processes are likely to have a greater administrative cost than the existing NCD process alone. Overall, the added responsibilities of the TCET process will compound agency resource gaps that exist within the CAG currently.

The CAG would benefit from an increase to its budget. Currently, the CAG's budget is not made available to the public, and therefore it is unclear how much funding CMS designates for the CAG or how much additional funding the CAG might require. However, in order to increase the CAG budget, CMS could internally designate a larger share of its annual mandatory or discretionary appropriations or Congress could act to specifically appropriate funds to the CAG. We believe CMS is unlikely to re-direct existing funding to the CAG given the agency's many concurrent obligations, and therefore Congressional appropriation is the most direct path towards increasing CAG's resources. Congress could start with an appropriation of several million dollars per year and require certain performance metrics to be achieved.

This recommendation may be accomplished through one of three policymaking approaches involving CMS and/or Congress.

- CMS reallocates its program management budget to increase funding for the NCD process.
- Congress provides additional funding for CMS's program management budget through the appropriations process, and a directive that CMS allocate some portion of the additional funding to the NCD process.
- Congress specifically earmarks new discretionary funding for the CMS NCD process through the appropriations process.

Approaches CMS may use to enhance agency staffing resources

Additional resources could also be allocated to the CAG in the form of clinical and research experts that are necessary for conducting the extremely detailed and specialized work of reviewing NCD requests. Four approaches may be available to CMS for accessing additional clinical and research experts:

- CMS could draw physicians or other clinicians specializing in the areas of medicine or the areas of research they require from other parts of CMS. It is unclear if these experts currently exist within the agency. We assume the agency has explored this approach.
- CMS could hire additional clinical and research experts as full time CMS employees from outside the agency. While this appears a reasonable approach, stakeholders we interviewed noted that CMS has had difficulty competing with other federal agencies, such as the FDA and the Health Resources and Services Administration (HRSA), for clinical and research experts. This difficulty stems from the fact that FDA and HRSA are Public Health Service agencies and as such they maintain "Title 42 authority" which enables these agencies to pay experts higher salaries and enables these agencies to hire consultants. Specifically, 42 U.S.C. 209(f) states "In accordance with regulations, special consultants may be employed to assist and advise in the operations of the Service. Such consultants may be appointed without regard to the civil-service laws."¹
- CMS could outsource NCD reviews to external consultants with the specific expertise needed for each review. To accomplish this, CMS would need for Congress to authorize the agency as a Public Health Service agency with Title 42 authority. This action would enable CMS to hire outside consultants at reimbursement rates above civil service rates.
- CMS could accredit third-party contractors to conduct relevant research and analysis on specific NCDs to supplement CMS technical expertise and expand its capacity. The third-party contractors would complete their background review and submit the analysis to CMS for final review and then to issue for comment. CMS may prioritize the utilization of the third-party contractors by type of NCD request (e.g., new vs. revision NCD requests) or by complexity level of the request. For example, the FDA's 501k reviews uses contractors for lower complexity reviews.

Further, in the context of generating additional resources for CAG, there may be ways in which CMS's NCD review process and the FDA's approval processes could be harmonized. Based on our analysis, we do not view FDA-like user fees as the immediate solution to the resource needs of CMS's NCD process. However, linking evidence review efforts within CMS's NCD review process to FDA's approval processes is a reasonable policy alternative. For example, there may be evidence the FDA approval processes are generating in the context of patient safety that might be relevant and useful to CMS as it reviews NCDs in the context of medical devices being reasonable and necessary. CMS has stated that it is working with FDA to explore linkages between these processes, and we believe this is a wise pursuit.

Appendix 1

Methodology

Literature review

HMA conducted an extensive literature review of journal articles as well as papers and reports released within the trade press to identify the key concerns of stakeholders and gain background the issue at hand. We also reviewed presentations and papers released by non-profit think tanks and government agencies that have weighed in on this issue or discussed the CMS NCD process in some way. Our literature review focused on contents released in the last five years, but did include older information if it was relevant for context.

Stakeholder analysis of comment letters to the MCIT Proposed Rule (2021)

HMA reviewed comments submitted by stakeholders pertaining to the 2020 MCIT Proposed Rule.^{li} We gathered viewpoints from hospital trade associations, payor trade associations, manufacturers and their trade associations, patient advocates, and physician societies. Comments were wide ranging, and many focused on the CED aspect of the NCD process.^{lii liii liv}

Interviews

HMA interviewed a wide range of experts with knowledge of the NCD process to gather their insight about the process, its shortcomings, and ways in which it might be improved. Experts included former staff at CMS, representatives employed by provider trade associations, a representative of a pharmaceutical manufacturer, a representative of a medical device manufacturer, representatives of a non-profit academic research organization, a representative of a law firm representing clients who utilize the Medicare coverage and benefit category processes, and representatives of a beneficiary advocacy organization. Interviews were conducted between February and April 2023.

Data Sources and Collection

To assess the complexity of the pool of NCD requests, the number of NCD requests being completed by CMS, and the length of time NCD requests spend in the NCD review process, HMA conducted an analysis of CMS's Medicare Coverage Database (MCD). The MCD is a publicly available dataset containing information on NCD requests that CAG has accepted for review. The MCD does not include NCD requests that are not accepted for review by CAG. For NCD requests in the MCD, the dataset describes the type and primary benefit category, the date in which the request was submitted, accepted for review, a proposed decision memo was released, and a final decision memorandum was released.

Appendix 2

Overview of Statutes and Regulations Related to the Medicare Coverage Process

Section 1862(l)(3) of the Social Security Act defines a national coverage determination (NCD) in general terms as a policy decision made by the Secretary of Health and Human Services (HHS) as to whether an item or service will be covered by the Medicare program. NCDs are to be made through an evidence-based process with opportunities for public participation. Further, through the NCD process, the Secretary is required to assess whether items or services are “reasonable and necessary.” The final decision memo must include the decision to grant, limit, or exclude coverage and summarize the public comments and include responses.^{lv}

Also specified in statute at Sections 1862(l)(3)(A) and 1862(l)(3)(B) of the Social Security Act are specific timing requirements that the CMS process must follow. NCDs are required to include an evidence review of the coverage requested that should take no more than six months after the date of the request, or nine months after the date of request if the review requires a technology assessment. Generally, CMS does not accept requests for coverage analysis if the device or pharmaceutical has not been deemed safe and effective by the FDA.^{lvi} In addition, the Secretary is required to post a draft of the proposed decision for a 30-day public comment period. Further, as defined by statute (Section 1862(l)(3)(C)), the Secretary must make a final coverage decision no later than 60 days after the close of the 30-day public comment period. In addition, the Secretary is statutorily required to submit an annual report to Congress on Medicare Coverage Determinations from CMS, consistent with Section 1869(f)(7) of the Social Security Act. As a part of this report, the Secretary must report the amount of time it took to complete and implement all NCDs.^{lvii}

Although the Social Security Act holds the HHS Secretary responsible for Medicare coverage decisions, the authority to conduct this work has been delegated to the CMS. In particular, the Coverage and Analysis Group (CAG) within the Centers for Clinical Standards and Quality (CCSQ) is responsible for the daily work of developing and implementing NCDs.^{lviii} This group consists of physicians and other clinicians, policy analysts and researchers dedicated to overseeing the Medicare coverage process. Ultimately, all of the CAG and CMS work is done under the authority in the law given to the Secretary.

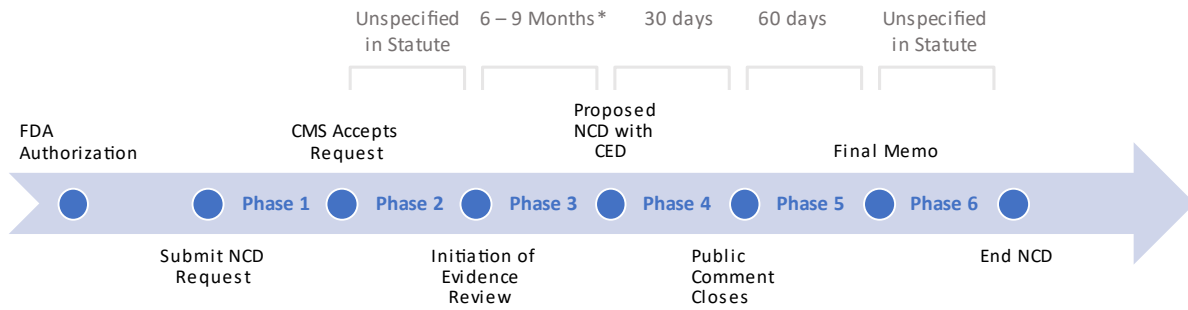
Regulations published by CMS establish procedural requirements for an NCD. CMS generally will allow a 30-day public comment when the NCD review is announced on the tracking sheet. The announcement of the NCD is when CMS initiates the evidence review process.^{lix} In addition, CMS regulations state that the agency’s decision memorandum will define if CMS is granting coverage, limiting coverage, requiring CED, or issuing a noncoverage determination.

Based on these statutory and regulatory requirements CMS’s NCD timeline spans six phases (See Figure 1). For coverage decisions that include a device, generally, it must first have received authorization from the FDA. After that, a stakeholder may submit a request to CMS’s CAG.

- Phase 1: The time between when the stakeholder submits the NCD request and when CMS’s CAG accepts the request.
- Phase 2: The period between when the CAG accepts the request and when the CAG formally initiates the evidence review of the medical device.
- Phase 3: The statutorily defined six-to-nine month period between when CMS’s evidence review begins and when CMS must release the draft NCD memo to the public, including 30-day public comment period, defined through regulation, when the NCD review is announced to the public.
- Phase 4: The statutorily defined 30-day period between when CMS must post the proposed NCD decision memo for each application and the end of the public comment period.

- Phase 5: The statutorily defined 60-day period CMS is allotted between when the public comment period ends and CMS must release the final NCD decision memo for each application.
- Phase 6: The period between an NCD becomes effective and the NCD is terminated.

Figure 2: National Coverage Determination Process



* Contains a 30-day Public Comment Period once CMS initiates evidence review.

Appendix 3

External NCD coverage requests exceeding 200 days

Table 2 External Coverage Requests with 200 Days or Greater from Request to Initiation of Evidence Review

Title	Total Days in Phase 1 & 2 - Request to Initiation of Evidence Review	Percent of Total Time in Phase 1 & 2
AlloMap® Molecular Expression Testing For Detection of Rejection of Cardiac Allografts	2824	94%
Seat Elevation Systems as an Accessory to Power Wheelchairs	699	-
Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches	584	59%
Heartsbreath Test for Heart Transplant Rejection	509	68%
Cochlear Implantation	490	70%
Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Oxygen)	484	65%
Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection	345	-
Autologous Blood-Derived Products for Chronic Non-Healing Wounds	330	47%
Screening for Colorectal Cancer - Blood-Based Biomarker Tests	322	50%
Intestinal and Multi-visceral Transplantation	286	51%
Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy	280	48%
Transcatheter Aortic Valve Replacement (TAVR)	245	41%
Screening for Hepatitis B Virus (HBV) Infection	238	49%
Cavernous Nerves Electrical Stimulation with Penile Plethysmography	232	47%
Aprepitant for Chemotherapy-Induced Emesis	230	49%
Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	224	-

Source: CMS Medicare Coverage Database, March 2023

Note: Cells with missing values for percent of total time in Phases 1 & 2 are the result of missing data in the respective cases' record.

Appendix 4

HMA Team Bios

Amy Bassano, Managing Director

Amy Bassano is the Managing Director for HMA's Medicare Strategic Focus Area. Ms. Bassano has been with HMA for 2 years and brings more than 20 years of experience in developing organizational vision and strategic plans, designing and implementing payment systems, and driving change in the healthcare delivery system. Ms. Bassano joins HMA after serving as the deputy director for the Center for Medicare and Medicaid Innovation (CMMI) at the Centers for Medicare & Medicaid Services (CMS). As senior executive at CMMI, she oversaw the development and implementation of value-based purchasing models for Medicare and Medicaid. She collaborated with states, health plans, purchasers, and international organizations to lead the national and international movement for value in healthcare. Ms. Bassano has more than 15 years at CMS and served in various Medicare leadership roles, including as director of the Hospital and Ambulatory Policy Group where she developed and implemented hospital, physician, Part B prescription drugs, clinical laboratory, and other acute care payment policies. Ms. Bassano earned a master's degree in policy studies from John Hopkins University and a bachelor's degree in history from Tufts University.

Zach Gaumer, Principal

Zach Gaumer is a Principal in HMA's Washington DC office. Mr. Gaumer has been with HMA for 4 years and supports clients on Medicare and Medicaid policy topics including reimbursement, coverage, and analytics. Prior to HMA, Mr. Gaumer was a Principal Policy Analyst at the Medicare Payment Advisory Commission (MedPAC) for over 11 years, supporting the U.S. Congress on Medicare reimbursement policy topics including the hospital, physician, ambulatory surgery center, and ambulance reimbursement systems as well as telehealth policy, emergency department policy, and medical device policy. Mr. Gaumer also spent 6 years at the U.S. Government Accountability Office evaluating various federal health care programs at the request of the U.S. Congress, including topics such as the Medicare Advantage program, specialty hospitals, and Accountable Care Organizations. Mr. Gaumer has a Master's degree in policy studies from Johns Hopkins University, majoring in health policy and international affairs policy. Mr. Gaumer has a Bachelor's degree from Kenyon College in History.

Melissa Mannon, Senior Consultant

Melissa Mannon is a Senior Consultant in HMA's Washington DC office. Ms. Mannon has been with HMA for four months and supports clients in design, development, implementation, and policy for payment innovations. She provides guidance on how to align payment with services that provide higher quality of life and outcomes for people seeking care and helps clients understand how Medicare and Medicaid payment policies - particularly APMs - and changes to those policies will impact their business and strategy. Before joining HMA, Ms. Mannon was director of the Office of Value Based Purchasing for Virginia's Department of Medical Assistance Service, Virginia's Medicaid agency, and oversaw \$350 million in financial incentives. She was responsible for leading the agency's development and implementation of payment and contract policy innovations that integrated performance accountability into the Virginia Medicaid program. She was the alternative payment models expert in Virginia and provided technical guidance to agency leadership, two governor's administrations, and legislators. Ms. Mannon earned a master's degree in public policy from George Washington University and a bachelor's degree in public health policy from Cornell College.

Constance Payne, Associate Principal

Constance Payne is an Associate Principal in HMA's Nashville, TN office. Dr. Payne has been with HMA for 3 months and brings highly successful, strategic solutions to an array of value-based care initiatives. Her extensive background includes pharmacy practice, federal healthcare policy, Medicaid, behavioral health services, and management consulting. Prior to joining HMA, Constance was a project delivery senior consultant in the Government and Public Services division at Deloitte. In this role, she created high quality rules design deliverables used to streamline the development and implementation of a cloud-based long-term services and supports solution. She helped translate designs for developers, walked through complex change requests with clients and helped develop training materials during a system transition. Additionally, Dr. Payne served as the opioid program director at United Healthcare, where she led the Tennessee community and state opioid program and managed the successful buildout of a statewide TennCare medication-assisted treatment (MAT) network. Dr. Payne earned a Doctor of Pharmacy and a bachelor's degree in pharmaceutical sciences from the University of Mississippi.

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Allie Macdonald is a Research Associate in HMA's Baltimore, MD office. Ms. Macdonald has been with HMA for 1 year and supports clients through literature reviews, qualitative and quantitative analysis, deliverable design, creation, and execution, as well as project management aid. She most often supports contracts in HMA's Medicare and Community Strategies Strategic Focus Areas. Prior to joining HMA, Ms. Macdonald held a leadership role at the University of Maryland's Public Health Beyond Borders student organization, where she led and collaborated on a variety of initiatives addressing public health concerns in the community of College Park, MD. Ms. Macdonald earned a bachelor's degree in public health science from the University of Maryland.

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