(4) Reimburse the Forest Service in a timely manner for the cost of abating an emergency.

(b) Compliance Officer determination of material noncompliance. When determining whether an operator or lessee has failed or refused to comply in a material respect with reclamation requirements or other requirements or standards identified in paragraph (a) of this section, the Compliance Officer shall advise the Bureau of Land Management that the entity has come into material compliance.

§ 228.114 Posting requirements.

The affected National Forest or Grassland ranger district office shall promptly post notices provided by the Bureau of Land Management of:

(a) Competitive lease sales which the Bureau of Land Management plans to conduct that include National Forest System lands. These must be posted for a minimum of 45 days prior to the sale;

(b) Substantial modifications in the terms which the Bureau of Land Management proposes to make for leases on National Forest System lands (43 CFR 3101.1–4). These must be posted for a minimum of 30 days prior to the sale; and

(c) Applications for Permits to Drill which the Bureau has received involving leases or agreements located on National Forest System lands according to provisions of Onshore Order 1. These must be posted for a minimum of 30 days.

§ 228.115 Information collection requirements.

The Office of Management and Budget reviewed and approved the information collection requirements contained in this subpart and assigned OMB Control No. 0596–0101. The collection of information allows the Forest Service to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). After the final rule is effective, the Medicare Coverage of Innovative Technology (MCIT) pathway would begin national Medicare coverage on the date of FDA market authorization and would continue for 4 years. We are also proposing regulatory standards to be used in making reasonable and necessary determinations under section

Operating plan means the following documents, providing that the document has been issued or approved by the Forest Service: A plan of operations as provided for in 36 CFR part 228, subparts A and D, and 36 CFR part 292, subparts C and G; a supplemental plan of operations as provided for in 36 CFR part 228, subpart A, and 36 CFR part 292, subpart G; an operating plan as provided for in 36 CFR part 228, subpart C, and 36 CFR part 292, subpart G; an amended operating plan and a reclamation plan as provided for in 36 CFR part 292, subpart G; a surface use plan of operations as provided for in 36 CFR part 228, subpart E; a surface use portion of a sundry notice as provided for in 36 CFR part 228, subpart E; a permit as provided for in 36 CFR 251.15; and an operating plan and a letter of authorization as provided for in 36 CFR part 292, subpart D.

* * * * *

James E. Hubbard,
Under Secretary, Natural Resources and Environment.

[FR Doc. 2020–18518 Filed 8–31–20; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–3372–P]

RIN 0938–AT88

Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). After the final rule is effective, the Medicare Coverage of Innovative Technology (MCIT) pathway would begin national Medicare coverage on the date of FDA market authorization and would continue for 4 years. We are also proposing regulatory standards to be used in making reasonable and necessary determinations under section

PART 261—PROHIBITIONS

5. The authority citation for part 261 continues to read as follows:


6. Amend § 261.2 by revising the definition for “Operating plan” to read as follows:

§ 261.2 Definitions.

* * * * *
1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 2, 2020.

ADDRESSES: In commenting, please refer to file code CMS–3372–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the “Submit a comment” instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3372–P, P.O. Box 8013, Baltimore, MD 21244–8013.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3372–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Linda Gousis or JoAnna Baldwin, (410) 786–2281 or CAGinquiries@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

The Administration is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. Section 6 of the October 3, 2019 Executive Order 13890 (E.O. 13890) “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors,” directs the Secretary to “propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients” including by “streamlining the approval, coverage, and coding process.” The E.O. 13890 explicitly includes making coverage of breakthrough medical devices “widely available, consistent with the principles of patient safety, market-based policies, and value for patients.”

The E.O. also directs the Secretary to “clarify the application of coverage standards.” We are responding directly to these directives by proposing a definition of the term “reasonable and necessary” to clarify coverage standards and proposing the Medicare Coverage of Innovative Technology (MCIT) pathway to accelerate the coverage of new, innovative breakthrough devices to Medicare beneficiaries. To date, the factors used in making “reasonable and necessary” determinations based on section 1862(a)(1)(A) of the Act have not been established in regulations for Medicare coverage purposes. The Secretary has authority to determine whether a particular medical item or service is “reasonable and necessary” under section 1862(a)(1)(A) of the Act.

When making coverage determinations, our policies have long considered whether the item or service is safe and effective, not experimental or investigational, and appropriate. For more information see the January 30, 1989 notice of proposed rulemaking (54 FR 4907). These factors are found in Chapter 13 of the Medicare Program Integrity Manual (PIM) at section 13.5.4—Reasonable and Necessary Provisions in LCDs as instructions for Medicare contractors. We are proposing to codify in regulations the Program Integrity Manual definition of “reasonable and necessary” with modifications, including to add a reference to Medicare patients and a reference to commercial health insurer coverage policies. We propose that an item or service would be considered “reasonable and necessary” if it is—(1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—• Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member; • Furnished in a setting appropriate to the patient’s medical needs and condition; • Ordered and furnished by qualified personnel; • One that meets, but does not exceed, the patient’s medical need; and • At least as beneficial as an existing and available medically appropriate alternative.

We also propose that an item or service would be “appropriate for Medicare patients” under (3) if it is covered in the commercial insurance market, except where evidence supports that there are clinically relevant differences between Medicare beneficiaries and commercially insured individuals. An item or service deemed appropriate for Medicare coverage based on commercial coverage would be covered on that basis without also having to satisfy the bullets listed above. We believe this definition is a significant step in meeting the E.O.’s directive to bring clarity to coverage standards. Stakeholders have expressed interest in codifying a definition of “reasonable and necessary” for many years. This proposed definition is familiar and functional, can satisfy that interest and meet the E.O.’s ask, while also aligning with the goals of MCIT by providing clarity and predictability for innovation, including for beneficiaries and innovators.

The proposed MCIT coverage pathway is specifically for Medicare coverage of devices that are designated as part of the Food and Drug Administration’s (FDA) Breakthrough Devices Program (hereafter referred to as “breakthrough devices”) and are FDA market authorized. The MCIT pathway would be voluntary and device manufacturers would notify CMS if they want to utilize this coverage option.

We propose that national Medicare coverage under the MCIT pathway would begin immediately upon the date of FDA market authorization (that is, the
date the medical device receives Premarket Approval (PMA); 510(k)
clearance; or the granting of a De Novo
classification request) for the
breakthrough device. This coverage
would occur unless the device does not
have a Medicare benefit category or is
otherwise excluded from coverage by
statute (that is, the Medicare statute
does not allow for coverage of the
particular device.) This coverage
pathway delivers on the
Administration’s commitment to give
Medicare beneficiaries access to the
newest innovations on the market,
consistent with the statutory definitions
of Medicare benefits. Because Medicare
is a defined benefit program, devices
that do not fit within the statutory
definitions may not be considered for
MCIT. As an example, medical
equipment for home use by the
beneficiary must be durable (that is,
withstand repeated use) for it to be
coverable by Medicare (as defined in
statutes and regulations by the
Secretary). At this time, we are limiting
MCIT to medical devices because that is
a category of products explicitly
identified in E.O. 13890, and we have
identified that breakthrough devices can
experience variable coverage across the
nation shortly after market
authorization.

We propose this MCIT pathway
because the prescribed statutory
timeframes for the National Coverage
Determination (NCD) process limit
CMS’ ability to institute immediate
national coverage policies for new,
innovative medical devices. NCDs and
Local Coverage Determinations (LCD)
take, on average, 9 to 12 months to
finalize. Because of this length of time,
there may be coverage uncertainty
between the period of FDA market
authorization and CMS finalization of an
NCD or a Medicare Administrative
Contractor’s (MACs) finalization of an
LCD. During this time period shortly
after market authorization, MACs make
coverage determinations on a case-by-
case (individual beneficiary) basis, but
those decisions do not usually establish
agency policy and therefore future claims
because a case-by-case decision is for
a particular beneficiary and their health
circumstances.

Over the past few years, CMS has
heard concerns from stakeholders that
breakthrough devices are not
automatically covered nationally by
Medicare once they are FDA market
authorized. Variation in coverage from
one jurisdiction to another is also a
concern. To date, 16 breakthrough
devices have also been market
authorized. The majority of these
breakthrough devices (10 devices)
experience variability in coverage for
two reasons. One reason is because the
breakthrough devices are coverable at
MAC discretion, like many other item
and services, on a case-by-case basis
(that is, the breakthrough device may be
covered for one patient, but not for
another within the same jurisdiction).
The other reason is because
breakthrough devices are used by a
hospital or other provider that operates
under a bundled payment system (such
as a diagnosis related group (DRG)
system), so there may be no separate
coverage policy for each item or service
that may be included in the bundled
payment. Another example of variable
coverage is for one breakthrough
device that is non-covered by a local policy
in Florida, but coverable at MAC
discretion on a case-by-case basis in
other jurisdictions. One breakthrough
device has national coverage through an
NCD. One breakthrough device has
uniform coverage because the same LCD has
been adopted in all jurisdictions.

There are three breakthrough
devices that do not have a Medicare benefit
category (for example, certain wearable
devices); therefore, those breakthrough
devices cannot be covered by the
Medicare program.

In contrast to varied local coverage,
the proposed MCIT would create a
pathway for immediate national
Medicare coverage of any FDA-market
authorized breakthrough device if the
device meets criteria outlined in this
proposal.

A. Statutory Authority

We are also proposing to establish in
regulations the factors we have
historically used in making “reasonable
and necessary” determinations under section 1862(a)(1)(A) of the Act, with
some modification. To summarize, this
section explains that Medicare payment
may be made under part A or part B for
any expenses incurred for items or
services that are reasonable and
necessary for the diagnosis or treatment
of illness or injury or to improve the
functioning of a malformed body
member. Thus, with some exceptions,
section 1862(a)(1)(A) of the Act requires
that an item or service be “reasonable
and necessary” to be covered by
Medicare. The courts have recognized
that the Secretary has significant
authority to determine whether a
particular item or service is “reasonable
and necessary.” (Heckler v. Ringer, 466
U.S. 602, 617 (1984). See also, Yale-New
Haven Hospital v. Leavitt, 470 F.3d 71,
94 (2d Cir. 2006); Kort v. Burwell, 209
F. Supp. 3d 901 (C.D. Cal. 2016) (The
statute vests substantial authority in the
Secretary.)). So even though section
1862(a)(1)(A) of the Act limits the scope
of Medicare coverage, the Secretary has
discretion to revise his/her
interpretation of the statute in order to
ensure adequate coverage for items and
services under Part A and Part B.

This proposal would provide national
Medicare coverage for breakthrough
devices that are FDA market-authorized
and used consistent with the FDA
approved or cleared indication for use
(also referred to as the “FDA-required
labeling”). This device coverage under
the MCIT pathway is reasonable and
necessary under section 1862(a)(1)(A) of
the Act because the device has met the
unique criteria of the FDA Breakthrough
Devices Program.

B. FDA Breakthrough Devices Program

Under the proposed MCIT coverage
pathway, CMS would coordinate with
FDA and manufacturers as medical
devices move through the FDA
regulatory process for Breakthrough
Devices to ensure seamless Medicare
coverage on the date of FDA market
authorization unless CMS determines
those devices do not have a Medicare
benefit category. The Breakthrough
Devices Program is an evolution of the
Expedited Access Pathway Program and
the Priority Review Program (section
515B of the Federal Food, Drug, and
Cosmetic Act (FDC Act), 21 U.S.C.
360e–3; see also final guidance for
industry entitled, “Breakthrough
Devices Program,” https://www.fda.gov/
downloads/MedicalDevices/Device
RegulationandGuidance/Guidance
Documents/UCM581664.pdf).

The FDA’s Breakthrough Devices
Program is not for all new medical
devices; rather, it is only for those that
the FDA determines meet the standards
for breakthrough device designation.
In accordance with section 3051 of the 21st
Century Cures Act (21 U.S.C. 360e–3),
the Breakthrough Devices Program is for
medical devices and device-led
combination products that meet two
criteria. The first criterion is that the
device provide for more effective
treatment or diagnosis of life-
threatening or irreversibly debilitating
human disease or conditions. The
second criterion is that the device must
satisfy one of the following elements: It

5 FDA Guidance for Industry, “Medical Product
Communications That Are Consistent With the
FDA-Required Labeling—Questions and Answers,”
available at https://www.fda.gov/media/133619/
download.

www.congress.gov/114/plaws/publ255/PLAW-
114publ255.pdf; see FDA Guidance for Industry
and Food and Drug Administration Staff,
Breakthrough Devices Program available at https://
www.fda.gov/medical-devices/how-study-and-
market-your-device/breakthrough-devices-program.
represents a breakthrough technology; no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or device availability is in the best interest of patients (for more information see 21 U.S.C. 360e–3(b)(2)). These criteria make breakthrough designated devices unique among all other medical devices.7 The parameters of the breakthrough devices program focus on innovations for patients, in turn, MCIT, focuses on these breakthrough devices consistent with E.O. 13890 and in order to streamline coverage of innovative medical devices.

C. Current Medicare Coverage Pathways

Currently, we utilize several coverage pathways for items and services, which includes medical devices. None of the coverage pathways described in this section offer immediate, predictable coverage concurrently with FDA market authorization. Like the proposed MCIT pathway would do. We summarize the other coverage pathways here to provide context for MCIT.

• National Coverage Determinations (NCDs): Section 1862(l)(6)(A) of the Act defines the term national coverage determination as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.” In general, NCDs are national policy statements published to identify the circumstances under which particular items and services will be considered covered by Medicare. Traditionally, CMS relies heavily on health outcomes data to make NCDs. Most NCDs have involved determinations under section 1862(a)(1)(A) of the Act, but NCDs can be made based on other provisions of the Act, and includes a determination that the item or service under consideration has a Medicare benefit category. The NCD pathway, which has statutorily prescribed timeframes, generally takes 9 to 12 months to complete.8
• Local Coverage Determinations (LCDs): Medicare contractors develop LCDs based on section 1862(a)(1)(A) of the Act that apply only within their geographic jurisdictions. (Sections 1862(l)(6)(B) and 1869(j)(2)(B) of the Act.) MACs will not need to develop LCDs for breakthrough devices when they are nationally covered through MCIT.

The MACs follow specific guidance for developing LCDs for Medicare coverage in the CMS Program Integrity Manual, and in some instances, an LCD can also take 9 to 12 months to develop (MACs must finalize proposed LCDs within 365 days from opening per Chapter 13—Local Coverage Determinations of the (PIM) 13.5.1). We note that the MCIT pathway will not alter the existing coverage standards in Chapter 13—Local Coverage Determinations of the PIM.9 That chapter will continue to be used in making determinations under section 1862(a)(1)(A) of the Act for other items and services at the local level.

• Claim-by-claim Adjudication: In the absence of an NCD or LCD, MACs would make coverage decisions under section 1862(a)(1)(A) of the Act and may cover or not cover items and services on a claim-by-claim basis. The majority of claims are handled through the claim adjudication process.

• Clinical Trial Policy (CTP) NCD 310.1: The CTP pathway can be used for coverage of routine care items and services (but generally not the services that are covered through the MCIT pathway was developed in 2000.10 This coverage pathway has not generally been utilized by device manufacturers because they usually seek coverage of the device, which is not included in this pathway.

• Parallel Review: Parallel review is a mechanism for FDA and CMS to simultaneously review the submitted clinical data to help decrease the time between FDA’s approval of a premarket application or granting of a de novo classification and the subsequent CMS NCD. Parallel Review has two stages: (1) FDA and CMS meet with the manufacturer to provide feedback on the proposed pivotal clinical trial within the FDA pre-submission process; and (2) FDA and CMS concurrently review (“in parallel”) the clinical trial results submitted in the PMA, or De Novo request. FDA and CMS independently review the data to determine whether it meets their respective Agency’s standards and communicate with the manufacturer during their respective reviews. This program is most successful for devices that have a significant amount of clinical evidence. (Candidates for parallel review would not be appropriate for simultaneous MCIT consideration.)

Even though CMS has multiple coverage pathways, at this time none are readily available to provide immediate national coverage for new breakthrough devices with a Medicare benefit category at the same time as FDA market authorization. Further, some of these new breakthrough devices are likely to have limited or developing bodies of clinical evidence because of the newness of the device; therefore, the MCIT pathway can support manufacturers that are interested in combining coverage with their own clinical study to augment clinical evidence of improved health outcomes, particularly for Medicare patients. Given this and existing coverage pathways, we seek comment from the public regarding if any of these existing pathways should be modified to achieve the goals set out by E.O. 13890.

D. MCIT Pathway

We propose that the MCIT pathway would provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continue for up to 4 years, unless we determine the device does not have a Medicare benefit category as determined by us as part of the MCIT pathway process. The MCIT pathway is voluntary (that is, manufacturers would affirmatively opt-in), and would be initiated when a manufacturer notifies CMS of its intention to utilize the MCIT pathway. (This notification process is described further in section III. of this proposed rule.) We would subsequently coordinate with the manufacturer regarding steps that need to be taken for MCIT implementation purposes. The frequency of subsequent engagement will be largely driven by whether the manufacturer has questions for CMS, or CMS and FDA. The timing of coverage will depend upon the timing of the FDA’s market authorization decision. Engagements can take place in the form of in-person meetings, phone calls, emails, etc. We intend to put devices that are covered through the MCIT pathway on the CMS website so that all stakeholders will be aware of what is covered through the MCIT pathway. Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during
coverage under the proposed MCIT pathway. However, we seek comment as to whether CMS should require or incentivize manufacturers to provide data about outcomes or should be obligated to enter into a clinical study similar to CMS’s Coverage with Evidence Development (CED) paradigm. We are aware some manufacturers may be required by the FDA to conduct post-market data collection as a condition of market authorization, and nothing in this proposed rule would alter that FDA requirement. Manufacturers are encouraged to develop the clinical evidence base needed for one of the other coverage pathways after the MCIT pathway ends. This evidence is encouraged not only for CMS and private commercial health insurer coverage policies but also to better inform the clinical community and the public generally about the risks and benefits of treatment. CMS encourages early manufacturer engagement, both before and after FDA market authorization, for manufacturers to receive feedback from CMS on potential clinical study designs and clinical endpoints that may produce the evidence needed for a definitive coverage determination after MCIT. This feedback would not involve CMS predicting specific coverage or non-coverage.

In order to further the goals of E.O. 13890, CMS proposes to rely on FDA’s breakthrough device designation and market authorization of those devices to define the universe of devices eligible for MCIT, except for those particular devices CMS determines do not have a Medicare benefit category or are statutorily excluded from coverage under Part A or Part B. In order to provide immediate national coverage to innovative medical devices, we propose to establish a time limit on how long a breakthrough device can be eligible for MCIT (that is, considered a breakthrough device for coverage purposes). MCIT has a time limit on newness similar to our New Technology Add-on Payment (NTAP) policy. Eligibility for the NTAP is also time limited and this time limit applies to all new technologies, including breakthrough devices, for which an application for additional payment is submitted. Additionally, the time-limited characteristic of MCIT will drive some manufacturers to leverage this period of coverage to demonstrate the value of their device in the competitive marketplace. The 4-year coverage period is particularly important for manufacturers of breakthrough devices that choose to further develop the clinical evidence basis on which the FDA granted marketing authorization. From our experience with clinical studies conducted as part of an NCD, 4 years is approximately the amount of time it takes to complete a study.

At the end of the 4-year MCIT pathway, coverage of the breakthrough device would be subject to one of these possible outcomes: (1) NCD (affirmative coverage, which may include facility or patient criteria); (2) NCD (non-coverage); or (3) MAC discretion (claim-by-claim adjudication or LCD). Manufacturers that are interested in a NCD are encouraged to submit a NCD request during the third year of MCIT to allow for sufficient time for NCD development. We seek public comment on whether CMS should open a national coverage analysis if a MAC has not issued an LCD for a breakthrough device within 6 months of the expiration date of the 4-year MCIT period.

In our analysis of the current coverage landscape to determine opportunities for innovation and efficiencies, we also considered modifying the coverage process for non-breakthrough devices (for example, PMAs because they are also new to the market), but ultimately determined that it was the unique characteristics of FDA designated breakthrough devices and their ability to serve unmet needs that resonated most with the E.O.’s direction to encourage innovation for patients. We also considered expedited coverage of newly market authorized and breakthrough devices when used in a clinical study.

We seek public comment on the proposed MCIT pathway, the considerations described, whether any of the existing coverage pathways should be modified to achieve the goals set out by the E.O., and alternatives to these proposals. We specifically seek public comment on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval) or all diagnostics, drugs and/or biologics. We seek data to support including these additional item categories in the MCIT pathway. Also, we specifically seek manufacturer input on whether an opt-in or opt-out approach would work best for utilizing the MCIT pathway. We believe manufacturers will welcome this new coverage pathway. We want to preserve manufacturers’ business judgment and not assume which Medicare coverage pathway a given manufacturer of a breakthrough device would prefer (if any). Therefore, we have proposed an opt-in approach with an email to CMS to indicate affirmative interest in coverage. We are interested in whether an opt-out approach would be less burdensome for stakeholders. If so, we encourage public comment on a process for stakeholders to opt-out of MCIT that would not be burdensome. Also, we seek public comment on whether, once a manufacturer has opted-out of coverage, it can subsequently opt-in to MCIT.

II. Provision of Proposed Regulations

A. Defining “Reasonable and Necessary”

As described in section I. of this proposed rule, the Secretary has authority to determine the meaning of “reasonable and necessary” under section 1862(a)(1)(A) of the Act. We are proposing to codify the longstanding Program Integrity Manual definition of “reasonable and necessary” into our regulations at 42 CFR 405.201(b), with modification. Under the current definition, an item or service is considered “reasonable and necessary” if it is—

• Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
• Furnished in a setting appropriate to the patient’s medical needs and condition;
• Ordered and furnished by qualified personnel;
• One that meets, but does not exceed, the patient’s medical need; and
• At least as beneficial as an existing and available medically appropriate alternative.

In addition to codifying the above criteria, we propose to include a separate basis under which an item or service would be appropriate under (3) above that is based on commercial health insurers’ coverage policies (that is, non-governmental entities that sponsor health insurance plans). The
commercial market analysis would be
initiated if an item/service fails to fulfill
the existing factor (3) criteria defining
appropriate for Medicare patients but
fulfills (1) safe and effective and (2) not
experimental or investigational. By
considering commercial health insurer
coverage policies, CMS would bring
together the expertise of private payers
and CMS. For example, in a recent NCD
on acupuncture for chronic low back
pain, CMS considered the technology
assessments and coverage criteria
among commercial health insurer
coverage policies.13 We believe that this
approach would be in line with E.O.
13890 that directs us to make
technologies “widely available, consistent
with the principles of patient
safety, market-based policies, and value
for patients.” Under this separate basis,
we propose that an item or service
would satisfy factor (3) if it is covered
under a plan(s) coverage policy if
offered in the commercial insurance
market, unless evidence supports that
differences between Medicare
beneficiaries and commercially insured
individuals are clinically relevant.
Under our proposal, we would exclude
Medicaid managed care, Medicare
Advantage, and other government
administered healthcare coverage
programs from the types of coverage
CMS would consider, as these enrollees
are not in the commercial market. In
the following paragraphs, we seek comment
on this proposal and on how best to
implement this mechanism.
We solicit comments on sources of
data that could be used to implement
this policy, and whether CMS should
make this information public and
transparent. We seek public comment
on the most appropriate source(s) for
these coverage policies and the best way
to determine which commercial plan(s)
we would rely on for Medicare
coverage.
We seek comment on whether
beneficiaries, providers, innovators, or
others wishing to gain coverage for an
item or service demonstrate that the
item or service is covered by at least one
commercial insurance plan policy. If
they can provide CMS with evidence of
commercial coverage or if CMS or its
MACs identify such coverage from its
review of compilations of health
insurance offerings or data from other
sources, CMS would consider factor (3)
to be satisfied.
We solicited comment on whether we
should limit our consideration of
commercial plan offerings or covered lives
to a subset of the commercial
market in the interest of simplicity,
including looking at geographic subsets,
subsets based on number of enrollees,
subsets based on plan type (HMO, PPO,
etc.), or other subsets of plans—including utilizing a singular plan.
We also seek comment on whether, given
considerations such the variation and
distribution of coverage policies and
access to innovations, we should only
cover an item or service if it is covered
for a majority, or a different proportion
such as a plurality, of covered lives
amongst plans or a majority, plurality,
or some other proportion of plan
offerings in the commercial market. (A
plan offering is a contract an insurer
offers to its enrollees, and a single
insurance company may provide many
different offerings.)
We also recognize that plan offerings
may impose certain coverage
restrictions on an item or service, e.g.
related to clinical criteria, disease stage,
or number and frequency of treatment.
As greater access to innovative
treatments provides beneficiaries with
more opportunity to improve health and
drive decisions, we would, when
coverage is afforded on the basis of
commercial coverage, adopt the least
restrictive coverage policy for the item
or service amongst the offerings we
examine. However, given potential
unreasonable or unnecessary utilization,
we also solicit comment on whether we
should instead adopt the most
restrictive coverage policy. We are
further considering, as another
variation, that if coverage restrictions
are largely similar and present across
the majority of offerings, CMS would
adopt these in its coverage policies. We
note that such coverage restrictions
include the basic requirement for
medical necessity at the level of
individual patients. Medicare will still
only pay for an item or service received
by a beneficiary if it is medically
necessary for the beneficiary. We seek
comment on whether, if we were to take
this approach, we should instead use a
proportion of a majority, as low as any
offering and as high as all
offerings, as a sufficient threshold. As a
final variation, we could defer, in the
absence of an NCD or national policy, to
the MACs to tailor the restrictions on
coverage based on what they observe in
the commercial market, just as we rely
on MACs with regards to the current
definition. We further solicit comment on
whether to grant coverage for an item or
service to the extent it meets the first
two factors and the commercial
coverage basis for the third factor.
Under this approach, we would only
use the current definition of
“appropriate” from the current PIM
when the exception for clinically
relevant differences between Medicare
beneficiaries and commercially insured
individuals applies (or if the
commercial coverage basis is
determined by a proportion like a
majority and there is insufficient
commercial coverage information
available). We note that referring to
commercial coverage in this way may
expand or narrow the circumstances
under which we will cover a particular
item or service and therefore solicit
comment on whether, under such an
approach, we should grandfather our
current coverage policies for items and
services. We also emphasize that the
MACs will continue to make
judgements in evaluating individual
claims for reimbursement, such that a
decision by CMS that an item or service
is reasonable and necessary in general
does not mean that it is reasonable and
necessary in all circumstances with
respect to individual claims for
reimbursement.
We seek public comment on the most
appropriate source(s) for these coverage
policies. Further, under our proposal,
each MAC would be responsible for
reviewing commercial offerings to
inform their LCDs or claim by claim
decisions, which would include
individual medical necessity decisions.
We may also allow the MACs to develop
approaches to address any or all of the
considerations outlined above, parallel
to their current practice of making
coverage decisions in the absence of an
NCD or national policy. We solicit
comment on the best role of the MACs,
along these lines or otherwise. We also
solicit comment on whether the
discretion to use the current criteria in
the PIM when there is evidence to
believe Medicare beneficiaries have
different clinical needs should be
exercised through the NCD process or in
other ways, as well as what quantum of
evidence should be sufficient.
In sum, we are proposing to define the
term “reasonable and necessary” based
on the factors currently found in the
PIM, plus an alternative basis for
meeting factor (3) based on any coverage
in the commercial market. We are also
soliciting comment on an alternative
under whether an item or service
satisfies the commercial coverage basis
for factor (3) is determined by how it is
treated across a majority of covered lives
amongst commercial plan offerings, as
well as an alternative whereby an item
or service would be appropriate for
Medicare patients to the extent it is
covered in the commercial market.

13CMS, Decision Memorandum for Acupuncture
for Chronic Low Back Pain, available at https://
www.cms.gov/medicare-coverage-database/details/
ncs-decision-memo.aspx?NCAId=295#:~:text=
When evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant, we would rely on the criteria in the current PIM. We would continue relying on local administration of the program by MACs (including coverage on a claim by claim basis and LCDs) and maintain our discretion to issue NCDs based on the final rule.

We solicit comment on this proposed definition of reasonable and necessary, and alternatives outlined above, as well as other mechanisms or definitions we could establish for the term “reasonable and necessary”, and the merits and drawbacks associated with each, including the potential impact on Medicare program expenses or complexity. We may finalize any variation or outgrowth of the policies described in this proposal, or some combination of these options in lieu of or in conjunction with our proposed definition.

B. Application of the “Reasonable and Necessary” Standard to the MCIT Pathway

We are proposing that, under the proposed MCIT pathway, an item or service that receives a breakthrough device designation from the FDA would be considered “reasonable and necessary” under section 1862(a)(1)(A) of the Act because breakthrough devices have met the FDA’s unique breakthrough devices criteria, and they are innovations that serve unmet needs. While other devices are still considered new to the market, for example, PMAs and even some 510(k)s, the devices designated by the FDA as breakthrough are representative of true innovations in the marketplace. This application of the “reasonable and necessary” standard in this way would ensure that the MCIT pathway can provide a fast-track to Medicare coverage of innovative devices that may more effectively treat or diagnose life-threatening or irreversibly debilitating human disease or conditions.

MCIT would improve healthcare for Medicare beneficiaries by providing national Medicare coverage for devices receiving the FDA breakthrough device designation, which are FDA market-authorized and used consistent with the FDA approved or cleared indication for use (also referred to as the “FDA required labeling”). 14 so long as the breakthrough device is described in an appropriate Medicare benefit category under Part A or Part B and is not specifically excluded by statute. We believe the criteria for qualification as a breakthrough device, as defined in section 515(b) of the Food, Drug and Cosmetic Act (21 U.S.C. 360e–3(b)) is sufficient to satisfy the elements of the “reasonable and necessary” standard. The first breakthrough device designation criterion is that a device must “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions” (21 U.S.C. 360e–3(b)(1)). The second criterion is that the device must satisfy one of the following elements: It represents a breakthrough technology: there are no approved or cleared alternatives; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or availability of the device is in the best interest of patients (21 U.S.C. 360e–3(b)(2)). Thus, breakthrough devices are those that HHS has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions. We believe that a device meeting these criteria, once also FDA market authorized, is “reasonable and necessary” for purposes of Medicare coverage.

This proposed rule recognizes that the FDA market authorization of breakthrough devices warrants immediate coverage under the “reasonable and necessary” clause in section 1862(a)(1)(A) of the Act. We previously stated that FDA determinations were not controlling determinations for Medicare coverage purposes under section 1862(a)(1)(A) of the Act. (For more information see the January 30, 1989 Federal Register (54 FR 4307) (“FDA approval for the marketing of a medical device will not necessarily lead to a favorable coverage recommendation . . . .”) and the August 7, 2013 Federal Register (78 FR 48165) (“However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.”) Under the Secretary’s broad authority to interpret section 1862(a)(1)(A) of the Act (supra section I.A.), we are revising our interpretation of the statute because of the practical concerns that our current standards have delayed access to a unique set of innovative devices that FDA has found to be safe and effective, and we believe are “reasonable and necessary” for purposes of Medicare coverage.

In light of E.O. 13890, the Secretary has determined that application of the current standards for making “reasonable and necessary” determinations may take too long following FDA market authorization of breakthrough devices. More importantly, the existing standard has not always provided Medicare beneficiaries adequate access to certain breakthrough medical devices when needed to improve health outcomes. We are proposing that breakthrough devices per se meet the reasonable and necessary standard in order to increase access and to reduce the delay from FDA market authorization to Medicare coverage.

C. MCIT Pathway

We are proposing the MCIT pathway to deliver on the Administration’s commitment to provide access to breakthrough devices to Medicare beneficiaries. The MCIT pathway provides up to 4 years of national coverage to newly FDA market authorized breakthrough devices. We are aware that this coverage may also facilitate evidence development on devices for the Medicare population because manufacturers can gather additional data on utilization of the device during the MCIT coverage period.

1. Definitions

In § 405.601(a) we are proposing that the MCIT pathway is voluntary. Operationally, we propose that manufacturers of breakthrough devices notify CMS of their intention to elect MCIT shortly after receiving notice from the FDA of being granted the breakthrough device designation. Ideally, this notification would be sent to CMS within 2 weeks of receiving breakthrough designation. However, entities would not be penalized for notifying CMS after that time. Alternatively, submitting a notification to CMS shortly before or concurrently with the date of the FDA marketing submission should also afford CMS sufficient time to operationalize MCIT for the device. The CMS Coverage and Analysis Group would establish an email box for these inquiries. This notification alerts CMS to offer guidance to manufacturers about the MCIT pathway and point to resources for coding and payment, which are key conversations to effectuate coverage upon FDA market authorization. We intend to utilize the existing coverage implementation processes to be prepared to offer coverage immediately upon the FDA market authorization. In § 405.601(b), we propose the following definitions for the purposes of 42 CFR part 405. We propose to define

“breakthrough device” as a medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e–3(d)(1))). We also propose to define, for the sake of clarity in the rule, that the acronym MCIT stands for Medicare Coverage of Innovative Technology.

2. MCIT Pathway Device Eligibility

In § 405.603(a) we propose that the pathway is available to devices that meet the definitions proposed in § 405.601. Based on the explicit mention of devices in E.O. 13890 and our interaction and feedback from stakeholders who expressed their concern that there is more uncertainty of coverage for devices than for other items and services (for example, diagnostics, drugs and biologics), this proposed policy is for devices only.

We propose in § 405.603(b) that the breakthrough devices that received FDA market authorization no more than 2 calendar years to the effective date of this subpart (the date the final rule is finalized) and thereafter will be eligible for coverage for claims submitted on or after the effective date of this rule. Claims for breakthrough devices with dates of service that occurred before the effective date of this rule would not be covered through MCIT. For example, a hypothetical breakthrough device that was FDA market authorized on October 1, 2018, and utilized on January 1, 2020, would not be eligible for coverage under MCIT because on January 1, 2020, the date of service, the final MCIT rule was not yet legally in effect. In contrast, a claim for utilization of the same hypothetical breakthrough device with a date of service on January 1, 2021 might be eligible for coverage if the claim occurred after the effective date of the rule (assuming that the effective date of the rule was prior to January 1, 2021). Breakthrough devices market authorized prior to the effective date of this rule will not be eligible for all 4 years of coverage. The 4-year period starts on the date of FDA market authorization. For example, a breakthrough device market authorized on October 1, 2018 would have claims covered through MCIT from the effective date of the final rule until October 1, 2022. If a manufacturer initially chooses to not utilize the MCIT pathway, and then chooses to do so some time after the breakthrough device’s market authorization, coverage still only lasts 4 years from the date of FDA market authorization. We seek comment on this eligibility criterion for devices and specifically the 2 year “lookback.”

We propose in § 405.603(c) that to be part of the MCIT pathway, the device must be used according to its FDA approved or cleared indication for use. We propose that the device is only covered for use consistent with its FDA approved or cleared indication for use because that is the indication and conditions for use that were reviewed by the FDA and authorized for marketing. Data are unlikely to be available to support extending beyond the FDA required labeling for breakthrough devices on the date of marketing authorization. Use of the device for a condition or population that is not labeled (“off-label”) will not be covered as that use would not be FDA authorized. We specifically seek comment on whether off-label use of breakthrough devices should be covered and, if so, under what specific circumstances and/or evidentiary support.

In § 405.603(d) and (e), we additionally propose limitations to what is coverable under the Act. In § 405.603(e), we are proposing that if CMS has issued an NCD on a particular breakthrough device, that breakthrough device is not eligible for MCIT. We are proposing this because, once the device has been reviewed by CMS for the FDA required approved or cleared indication for use; CMS has made a coverage determination based on the available evidence for that technology. We believe this would happen rarely because breakthrough devices are new technologies that are not likely to have been previously reviewed through the NCD process. In § 405.603(f), we acknowledge that the MCIT pathway may be excluded due to statute or regulation (for example, 42 CFR 411.15. Particular services excluded from coverage) and, like other items and services coverable by Medicare, the device must fall within the scope of a Medicare benefit category under section 1861 of the Act and the implementing regulations. If the device does not fall within a Medicare benefit category as outlined in the statute and implementing regulations, the device is not eligible for Medicare coverage; therefore, the device would not be eligible for the MCIT pathway.

3. General Coverage of Items and Services under the MCIT Pathway

We propose in § 405.605 that devices covered under the MCIT pathway are covered no differently from devices that are covered outside of MCIT. In other words, provided the items and services are otherwise coverable (that is, not specifically excluded and not found by CMS to be outside the scope of a Medicare benefit category), covered items and services could include the device, reasonable and necessary surgery to implant the device, if implantable, related care and services costs of the device (for example, replacing reasonable and necessary parts of the device such as a battery), and coverage of any reasonable and necessary treatments due to complications arising from use of the device. What the MCIT pathway offers compared to other pathways is predictable national coverage simultaneous with FDA market authorization that will generally last for a set time period.

The proposed MCIT pathway would support and accelerate beneficiary access to certain innovative devices. CMS encourages manufacturers that have breakthrough devices covered under MCIT to develop additional data for the healthcare community.

4. MCIT Pathway for Breakthrough Devices: 4 Years of Coverage

In § 405.607(a), we propose that the MCIT pathway for coverage would begin on the same date the device receives FDA market authorization. We propose this point in time to ensure there is no gap between Medicare coverage and FDA market authorization. This supports the MCIT pathway’s focus of ensuring beneficiaries have a predictable access to new devices.

We propose in § 405.607(b)(1) that the MCIT pathway for breakthrough devices ends 4 years from the date the device received FDA market authorization. We propose this 4 year time period because it could allow manufacturers to develop clinical evidence and data regarding the benefit of the use of their device in a real world setting. For example, we believe 4 years would allow most manufacturers sufficient time to complete FDA required post-approval or other real-world data collection studies that may have been a condition of FDA market authorization. This assumption is based upon our historical experience with studies conducted through coverage with evidence development (CED). Further, this time period allows Medicare to support manufacturers that, whether required by the FDA or not, have an interest in better understanding the health outcomes of their device in the Medicare population, including impacts on patient-reported and longer-term outcomes.

Further, § 405.607(b) proposes reasons that the MCIT pathway may end prior to 4 years. This includes circumstances whereby the device becomes subject to an NCD, regulation, statute, if the device can no longer be lawfully marketed.
D. Summary

In summary, the MCIT pathway would provide immediate Medicare coverage of newly FDA market authorized breakthrough devices for 4 years. We seek public comment on all of our proposals. In particular, we seek feedback on whether the proposed 4 year coverage period is sufficient. We also look to stakeholders and the public to determine the level of interest and expected use of the proposed MCIT pathway so the agency can begin to estimate the level of needed resources to support successful implementation. We are also seeking public comments on our proposal to codify in regulations the standards we have historically used in making reasonable and necessary decisions under Part A and Part B under section 1862(a)(1)(A) of the Act. After considering public comments we would prepare a final rule that we expect would be effective 60 days after publication of the final rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

This proposed coverage pathway allows for a voluntary participation and therefore necessitates that manufacturers of breakthrough devices notify CMS of their intent to enter the MCIT pathway. Therefore, the burden associated with notifying CMS is the time and effort it would take for each of the organizations to send CMS an email or letter. We anticipate two MCIT pathway participants in the first year based upon the number of medical devices that received FY2020 NTAP and were non-covered in at least one MAC jurisdiction by LCDs and related articles.

We estimate notifying CMS of intent to participate in MCIT would involve 15 minutes at $69.72 per hour by a compliance officer. In this regard, we estimate 15 mins per notification at a cost of $17.43 per organization (0.25 hours × $69.72). In aggregate, we estimate 0.5 hours (0.25 hours × 2 submissions) at $34.86 ($17.43 × 2 submissions).

After the anticipated initial 2 submitters, over the next 3 years we expect 3 submitters in year 2, 4 submitters in year 3, and 5 submitters in year 4 to notify CMS of interest in the MCIT pathway. We expect this increase in submitters each year to level off at this point. In this regard, we estimate the same 0.25 hours per submission at a cost of $17.43 per organization. Similarly, in aggregate, we estimate, for year 2 (0.75 hours at $52.29 an hour), for year 3 (1.0 hour at $69.72 an hour), and for year 4 (1.25 hours at $87.15 an hour).

The proposed requirements and burden will be submitted to OMB under control number 0938–NEW.

We are requesting public comments on these information collection and recordkeeping requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–3372–P, Fax: (202) 395–6974; or Email: OIHA_submission@omb.eop.gov.

Comments must be received on/by November 2, 2020.

IV. Regulatory Impact Statement

This proposed rule makes Medicare coverage policy updates pursuant to the authority at section 1862(a)(1)(A) of the Act. We are using regulatory action per the October 3, 2019 “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors” to address the increasing need for a swift Medicare coverage mechanism to allow beneficiaries across the nation to access breakthrough devices faster after FDA market authorization. This proposed rule addresses that need by establishing a coverage pathway that will allow immediate beneficiary access to FDA market authorized breakthrough devices.

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202(b) of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4),
Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule does reach the economic threshold and thus is considered a major rule.

Regulatory alternatives to this proposed rule were to combine Medicare coverage with clinical evidence development under section 1862(a)(3), to take no regulatory action at this time, or to adjust the duration of the MCIT pathway. Combining coverage with clinical evidence development would have met the E.O. 13890 overarching goal of beneficiary access to breakthrough devices. However, this alternative did not meet the other E.O. 13890 aims of minimizing time between FDA market authorization and Medicare coverage and wide availability. The timing of coverage would depend upon the manufacturer being able to initiate a clinical study and the infrastructure necessary to participate in the clinical study. CMS chose to not to pursue combining coverage with evidence development for breakthrough devices because we wanted to meet the timing and wide availability aims of E.O. 13890. CMS also considered taking no regulatory action and trying to leverage the existing Medicare coverage pathways or proposing sub-regulatory policies to achieve the streamlined coverage process described in E.O. 13890. Taking no action would not have resulted in the desired national coverage and access envisioned in E.O. 13890 because, as described in this preamble, the existing coverage pathways do not consistently provide swift, national beneficiary access to innovative devices. As discussed elsewhere in the preamble, the nature of the problem being addressed by this proposed regulation is a potential delay between a milestone such as FDA market authorization and CMS coverage; as such, we request comment on a policy option of shortening the duration of the MCIT pathway from the proposed 4 years to 1 year.

In addition to the alternatives just discussed, there are various possibilities regarding how to change the definition of “reasonable and necessary”—for example, whether to include a new aspect of the proposed definition that focuses on commercial insurance coverage practices. As noted earlier in the preamble, the goal of this revision is to expand coverage. However, the nuances of the definition would affect the magnitude of the impact and we request comment that would facilitate quantification of effects and comparison of alternatives at the final rule stage.

The impact of implementing the MCIT pathway is difficult to determine without knowing the specific technologies that would be covered. In addition, many of these technologies would be eligible for coverage in the absence of this rule, such as through a local or national coverage determination. Determining the impact for certain items may be the acceleration of coverage or adoption by just a few months. Furthermore, some of these devices would be covered immediately if the MACs decide to pay for them, which would result in no impact on Medicare spending for devices approved under this pathway. However, it is possible that some of these innovative technologies would not otherwise be eligible for coverage in the absence of this rule. Because it is not known how these new technologies would otherwise come to market and be reimbursed, it is not possible to develop a point estimate of the impact. In general, we believe the MCIT coverage pathway would range in impact from having no impact on Medicare spending, to a temporary cost for innovations that are adopted under an accelerated basis.

The decision to enter the MCIT pathway is voluntary for the manufacturer. Because manufacturers typically join the Medicare coverage pathway that is most beneficial to them, this would result in selection against the existing program coverage pathways (to what degree is unknown at this point). In addition, the past trend of new technology costing more than existing technology could lead to a higher cost for Medicare if this trend continued for technologies enrolling in the MCIT pathway. Nevertheless, new technology may also mitigate ongoing chronic health issues or improve efficiency of services thereby reducing some costs for Medicare.

In order to demonstrate the potential impact on Medicare spending, the CMS Office of the Actuary (OACT) developed three hypothetical scenarios that illustrate the impact of implementing the proposed MCIT pathway. Scenarios two and three assume that the device would not have been eligible for coverage in the absence of this proposed rule. (See Table 2) The illustration used the new devices that applied for a NTAP in FY 2020 as a proxy for the new devices that would utilize the MCIT pathway. The submitted cost and anticipated utilization for these devices was published in the Federal Register. In addition, we assumed that two manufacturers would elect to utilize the MCIT pathway in the first year, three manufacturers in the second year, four manufacturers in the third year, and five manufacturers in the fourth year each year for all three scenarios. This assumption is based on the number of medical devices that received FY 2020 NTAP and were non-covered in at least one MAC jurisdiction by LCDs and related articles and our impression from the FDA that the number of devices granted breakthrough status is increasing. For the first scenario, the no-cost scenario, we assumed that all the devices would be eligible for coverage in the absence of the proposed rule. If the devices received payment nationally and at the same time then there would be no additional cost under this pathway. For the second scenario, the low-cost scenario, we assumed that the new technologies would have the average costs ($2,044) and utilization (2,322 patients) of similar technologies included in the FY 2020 NTAP application cycle. Therefore, to estimate the first year of MCIT, we multiplied the add-on payment for a new device by the anticipated utilization for a new device and at the same time then there would be no additional cost under this pathway. For the second scenario, the high-cost scenario, we assumed the new technologies would receive the maximum add-on payment from the FY 2020 NTAP application cycle ($22,425) and the highest utilization of a device (6,500 patients). Therefore, to estimate the first year of MCIT, we estimated similarly ($22,425 × 6,500 patients × 2 = $ 291.5 million). For subsequent years, we increased the number of anticipated devices in the pathway by three, four, and five in the last two scenarios until 2024.


16 An indirect cost of the proposed rule would be increased distortions in the labor markets taxed to support the Medicare Trust Fund. Such distortions are sometimes referred to as marginal excess tax.
not taking into account inflation, the illustration does not reflect any offsets for the costs of these technologies that would be utilized through existing authorities nor the cost of other treatments (except as noted). It is not possible to explicitly quantify these offsetting costs but they could substantially reduce or eliminate the net program cost. However, by assuming that only two to five manufacturers will elect MCIT coverage, we have implicitly assumed that, while more manufacturers could potentially elect coverage under MCIT, the majority of devices would have been covered under a different coverage pathway. Therefore, a substantial portion of the offsetting costs are implicitly reflected. Based on this analysis, there is a range of potential impacts of the proposed MCIT coverage pathway as shown in Table 2. The difference between the three estimates demonstrates how sensitive the impact is to the cost and utilization of these unknown devices.

### Table 2— Illustrated Impact on the Medicare Program by Proposed MCIT Coverage Pathway

<table>
<thead>
<tr>
<th>Scenario</th>
<th>FY 2021 (in millions)</th>
<th>FY 2022 (in millions)</th>
<th>FY 2023 (in millions)</th>
<th>FY 2024 (in millions)</th>
</tr>
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<tbody>
<tr>
<td>No-cost Scenario</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Low-cost Scenario</td>
<td>9.5</td>
<td>23.7</td>
<td>42.7</td>
<td>66.4</td>
</tr>
<tr>
<td>High-cost Scenario</td>
<td>291.5</td>
<td>728.8</td>
<td>1,311.9</td>
<td>2,040.7</td>
</tr>
</tbody>
</table>

We believe the assumptions used in the three scenarios are reasonable to show the possible wide range of impacts for implementing this proposed pathway, in particular for a technology that would not have otherwise been eligible for coverage.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Some hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $75 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We reviewed the Small Business Administration’s Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) Codes to determine the NAICS U.S. industry titles and size standards in millions of dollars and/or number of employees that apply to small businesses that could be impacted by this rule. We determined that small businesses potentially impacted may include surgical and medical instrument manufacturers (NAICS code 339112, dollars not provided/1,000 employees), Offices of Physicians (except Mental Health Specialists) (NAICS code 621111, $12 million/employees not provided), and Freestanding Ambulatory Surgical and Emergency Centers (NAICS code 621493, $16.5 million/employees not provided).

During the first 4 years of MCIT, we anticipate approximately 14 surgical and medical instrument manufacturers may participate, and based off of U.S. Census data, the majority of this businesses type are small businesses with less than 1,000 employees (968 out of 1,093 businesses have less than 500 employees). As such, this proposed rule would impact less than 5 percent of these businesses, and the revenue impact, if any, would not be negative. Rather, it would be a positive impact because MCIT would provide Medicare coverage (and subsequent payment) to providers who purchase the devices from these manufacturers. For Offices of Physicians (except Mental Health Specialists) and Freestanding Ambulatory Surgical and Emergency Centers that may be providing the breakthrough devices, the majority are small businesses with less than 1,000 employees (4,060 out of 4,385 and 160, 367 out of 161, 286 have less than 500 employees, respectively). Given that we estimate, at most in the high-cost scenario, that 6,500 beneficiaries would utilize breakthrough devices through MCIT per year, and even if each beneficiary were to access services at only one of these small businesses (that is, no two beneficiaries used the same office or center), still less than 5 percent of these small businesses would be impacted by MCIT. As such, the revenue impact, if any, would not be negative, rather, it would be a positive impact because MCIT would provide Medicare coverage (and subsequent payment) to providers. Overall, this proposed rule results in a payment, not a reduction in revenue. We are not preparing a further analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule will not have a significant negative economic impact on a substantial number of small entities because small entities are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business through this proposed rule. Rather, for small entities that develop or provide breakthrough devices to patients, this proposed rule is a means for the device to be covered through the Medicare program, which does not detract from revenue and could be viewed as a positive economic impact. With the limited information we had to base this estimate, we solicit public comment on improvements to this estimate for the final rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as one with less than 25 percent of the estimated transfer attributed to a policy change; the Circular goes on to direct the inclusion of estimated METB change in supplementary analyses. If secondary costs—such as increased marginal excess tax burden in the case of this proposed rule—are included in regulatory impact analyses, then secondary benefits must be as well, in order to avoid inappropriately skewing the net benefits results, and including METB only in supplementary analyses provides some acknowledgement of this potential imbalance.


19 Ed.
as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals because small rural hospitals are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business through this proposed rule. Obtaining breakthrough devices for patients is at the discretion of providers. We are not requiring the purchase and use of breakthrough devices. Providers should continue to work with their patients to choose the best treatment. For small rural hospitals that provide breakthrough devices to their patients, this proposed rule is a means for the device to be covered through the Medicare program.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold was approximately $156 million. This proposed rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 (E.O. 13771), titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule, if finalized as proposed, is expected to impose no more than de minimis costs and thus be neither an E.O. 13771 regulatory action nor an E.O. 13771 deregulatory action.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

§ 405.201 Scope of subpart and definitions.

1. The authority for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.201 is amended in paragraph (b) by adding the definition of “Reasonable and necessary means that an item or service is considered—

(a) Safe and effective;

(b) Except as set forth in § 411.15(o) of this chapter, not experimental or investigational; and

(c) Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it

(i) Meets all of the following criteria:

(A) Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the

(B) Furnished in a setting appropriate to the patient’s medical needs and condition;

(C) Ordered and furnished by qualified personnel;

(D) One that meets, but does not exceed, the patient’s medical need; and

(E) At least as beneficial as an existing and available medically appropriate alternative; or

(ii) Is covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.

3. Subpart F, consisting of §§ 405.601–405.607, is added to read as follows:

Subpart F—Medicare Coverage of Innovative Technology

Sec. 405.601 Medicare coverage of innovative technology.

405.603 Medical device eligibility.

405.605 Coverage of items and services.

405.607 Coverage period.

Subpart F—Medicare Coverage of Innovative Technology

§ 405.601 Medicare coverage of innovative technology.

(a) Basis and scope. Medicare coverage of innovative technology (MCIT) is a program that provides national, time-limited coverage under section 1862(a)(1)(A) of the Act for certain breakthrough medical devices. Manufacturer participation in the pathway for breakthrough device coverage is voluntary.

(b) Definitions. For the purposes of this subpart, the following definitions are applicable:

Breakthrough device means a device that receives such designation by the Food and Drug Administration (FDA) (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e–3(d)(1)).

MCIT stands for Medicare coverage of innovative technology.

§ 405.603 Medical device eligibility.

The MCIT pathway is available only to medical devices that meet all of the following:

(a) That are FDA-designated breakthrough devices.

(b) That are FDA market authorized at most [date 2 years prior to effective date] and thereafter.

(c) That are used according to their FDA approved or cleared indication for use.

(d) That are within a Medicare benefit category.

(e) That are not the subject of a Medicare national coverage determination.

(f) That are not otherwise excluded from coverage through law or regulation.

§ 405.605 Coverage of items and services.

Covered items and services furnished within the MCIT pathway may include any of the following, if not otherwise excluded from coverage:

(a) The breakthrough device.

(b) Any reasonable and necessary procedures to implant the breakthrough device.
(c) Reasonable and necessary costs to maintain the breakthrough device.
(d) Related care and services for the breakthrough device.
(e) Reasonable and necessary services to treat complications arising from use of the breakthrough device.

§ 405.607 Coverage period.

(a) Start of the period. The MCIT pathway begins on the date the breakthrough device receives FDA market authorization.
(b) End of the period. The MCIT pathway for a breakthrough device ends as follows:

(1) No later than 4 years from the date the breakthrough device received FDA market authorization.
(2) Prior to 4 years if a manufacturer withdraws the breakthrough device from the MCIT pathway.
(3) Prior to 4 years if the breakthrough device becomes the subject of a national coverage determination or otherwise becomes noncovered through law or regulation.


Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.


Alex M. Azar II,
Secretary, Department of Health and Human Services.

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DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

50 CFR Part 17

[FF09E21000 FXES11110900000 201]

Endangered and Threatened Wildlife and Plants; Two Species Not Warranted for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce 12-month findings on petitions to add Big Cypress epidendrum (Epidendrum strobiliferum) and Cape Sable orchid (Trichocentrum undulatum) to the List of Endangered and Threatened Plants under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the Big Cypress epidendrum or Cape Sable orchid. However, we ask the public to submit to us at any time any new information relevant to the status of either of the species mentioned above or their habitats.

DATES: The findings in this document were made on September 1, 2020.

ADDRESSES: Detailed descriptions of the basis for these findings are available on the internet at http://www.regulations.gov under the following docket numbers:

<table>
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<th>Species</th>
<th>Docket No.</th>
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Please submit any new information, materials, comments, or questions concerning this finding to the person specified under FOR FURTHER INFORMATION CONTACT.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 et seq.), we are required to make a finding whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (“12-month finding”). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted but precluded. We must publish a notice of these 12-month findings in the Federal Register.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines “species” as any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines “endangered species” as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and “threatened species” as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;
(B) Overutilization for commercial, recreational, scientific, or educational purposes;
(C) Disease or predation;
(D) The inadequacy of existing regulatory mechanisms; or
(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species’ continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term “threat” to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term “threat” includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term “threat” may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an “endangered species” or a “threatened species.” In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The