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Final MCIT Rule Authorizes New Medicare Coverage Pathway

On January 14, 2021, the *Centers for Medicare & Medicaid Services* (CMS) published a final rule entitled, "*Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary*" to expedite Medicare coverage for *"new and innovative technologies*."[1] This final rule is in response to the October 3, 2019 Executive Order entitled, "*Executive Order on Protecting and improving Medicare for Our Nation's Seniors*,"[2] which directed the Secretary of the *Department of Health & Human Services* (HHS) to propose regulation that will encourage innovation and streamline the approval, coverage, and coding process for items and services eligible for Medicare coverage.[3]

In an effort to meet these directives, this final rule: (1) introduces the Medicare Coverage of Innovative Technology (MCIT) Pathway, a pathway that will provide *Food and Drug Administration* (FDA)-designated breakthrough medical devices four-year, nationwide Medicare coverage on the same day as FDA market authorization; and, (2) codifies the term "*reasonable and necessary*," a criterion used to determine whether a device is eligible for Medicare coverage.[4]

Current Pathways to Medicare Coverage

Current rules specify that Medicare coverage for a medical device can be awarded through one of several pathways described below:[5]

(1) National Coverage Determinations (NCDs) – A nationwide determination as to whether or not an item or service will be covered by Medicare. NCDs typically take 9-12 months to complete;[6]

(2) Local Coverage Determinations (LCDs) – Coverage that is awarded for a specific geographic region by a Medicare Administrative Contractor (MAC). This process can take upwards of 9 to 12 months to complete;[7]

(3) Claim-by-Claim Adjudication – Coverage that is awarded by a MAC on a claim-by-claim basis. This coverage pathway accounts for the majority of claims;[8] and,

(4) Parallel Review – A process that allows the FDA and CMS to simultaneously review submitted clinical data in an effort to reduce the time between FDA approval and a CMS NCD. This process generally requires that devices have a significant amount of clinical evidence.[9]

These pathways often result in an expensive and lengthy process for innovators.[10] Because of the administrative burden these pathways place on innovators and device manufacturers, Medicare beneficiaries' access to breakthrough medical devices is delayed.[11] Moreover, the LCD and Claim-by-Claim Adjudication pathways create discontinuity in Medicare coverage across geographic areas and among Medicare beneficiaries.[12]

The MCIT Pathway will provide four-year, nationwide coverage for eligible devices as early as the same day as FDA market authorization.[13] Not only will this eliminate the lag between FDA market authorization and Medicare coverage (and reimbursement), but it will also remove the administrative burden of securing an LCD for each geographic area.[14]

MCIT Pathway Eligibility

It is important to note that not all devices will be eligible for the MCIT Pathway. For a device to be eligible for coverage under the pathway, the device must: (1) have a Medicare benefit category; and, (2) be an FDA-designated breakthrough medical device.[15]

Only devices that are covered by Medicare benefits will be eligible for the MCIT Pathway.[16] For example, statutory definitions of Medicare benefits specify that home medical equipment must be durable in order to be covered under Medicare.[17] As a result, single-use home medical equipment does not fall within a Medicare benefit category, thus making it ineligible for the MCIT Pathway.[18]

The *Breakthrough Device Program* is a voluntary FDA program that provides an expedited FDA review and authorization process for designated medical devices and device-led combination products (including some diagnostic tests).[19] To be eligible for the breakthrough device designation, the device:

(1) Must provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating conditions; and,

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(2) Must:

(a) Represent breakthrough technology;

(b) Have no approved or cleared alternative;

(c) Offer significant advantages over existing alternatives; or,

(d) Show that availability is in the best interest of patients.[20]

The unique attributes required by the FDA Breakthrough Devices Program will exclude the majority of medical devices from being eligible for the MCIT Pathway.[21] However, as participation in the Breakthrough Devices Program continues to grow, the number of devices eligible for the MCIT Pathway will as well.[22] As of May 2020, 298 devices had been awarded breakthrough device distinction, including 136 devices in 2019 and 50 devices in the first five months of 2020.[23] With breakthrough device distinction being a prerequisite for the attractive MCIT Pathway, it is likely that participation in the Breakthrough Devices Program will continue to grow.

In addition to the breakthrough devices that received FDA market authorization on or after the MCIT final rule's effective date – March 15, 2021 – breakthrough devices that were approved in the two years prior to the final MCIT rule's effective date will also be eligible for the MCIT Pathway.[24]

Although some commenters expressed a desire for the MCIT Pathway to be available to non-breakthrough medical devices, CMS held the eligibility requirements for the MCIT firm between the proposed and final rule, citing the immediate need for more rapid approval of breakthrough medical devices while acknowledging the needs to promote innovation of all Medicare eligible items and services.[25]

Coverage under the MCIT Pathway and Beyond

As previously stated, under the MCIT Pathway, device manufacturers will be eligible for nationwide Medicare coverage as early as the same day of FDA market authorization.[26] However, device manufacturers can select the date on which they would like Medicare coverage to begin within two years of FDA market authorization.[27] This will allow manufacturers to align their manufacturing and distribution cycles with the start of their Medicare coverage period.[28]

Medicare coverage under the MCIT Pathway will last for four years.[29] At the end of those four years, innovators can continue Medicare coverage through an NCD, LCDs, or Claim-by-Claim Adjudication.[30]

The MCIT Pathway allows innovators to collect any necessary clinical data to support their application for Medicare coverage post-MCIT, during the four years of pathway participation (while receiving Medicare reimbursement for those devices).[31] Additionally, innovators will be able to begin pursuing an NCD or LCDs during their four years of coverage under the MCIT Pathway, removing the burden of no Medicare coverage (and no reimbursement) from breakthrough-device innovators.[32]

Codifying the Definition of "Reasonable and Necessary"

In addition to establishing the MCIT Pathway, the MCIT final rule codified the definition of "*reasonable and necessary*."[33] In order for an item or service to be covered by Medicare, the item or service in question must be *"reasonable and necessary for the diagnosis or treatment of illness or injury*."[34]

Under the current definition of "*reasonable and necessary*," as defined in the Program Integrity Manual, a service or item is considered "*reasonable and necessary*" if it is: (1) safe and effective; (2) not experimental or investigational; and, (3) appropriate for Medicare beneficiaries.[35]

An item or service is considered appropriate for Medicare beneficiaries if it:

(1) Is provided in compliance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition;
(2) Is provided in a setting appropriate for the patient's medical needs and conditions;
(3) Is ordered and administered by qualified personnel;
(4) Meets but does not exceed the patient's medical need; and,
(5) Provides a similar or greater level of benefit as an existing and available alternative.[36]

The MCIT final rule will not only codify this existing, long standing definition, but will also expand the criteria for "appropriate" items and services.[37] An item or service that does not satisfy the previously-listed criteria will be considered "appropriate" if it is covered under a commercial insurance plan's coverage policy.[38]

The expansion of criterion 3 (an item or service must be appropriate for Medicare beneficiaries) of the "*reasonable and necessary*" definition will expand Medicare beneficiaries' access to medically beneficial items and services by allowing items and services that would not otherwise be eligible for Medicare coverage, to be covered, without compromising the safety of beneficiaries.[39]

Impact of MCIT Final Rule

Medical technology industry stakeholders have voiced support for the new MCIT Pathway since it was first proposed in August 2020.[40] Interest groups, including the Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA), and the National Venture Capital Association (NVCA), submitted comments during the comment period, expressing enthusiasm for the new pathway as well as some reservations over the restrictions of coverage under the MCIT Pathway.[41]

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Overall, the new MCIT Pathway will allow Medicare beneficiaries to have access to breakthrough medical technology much earlier than they would under the currently available pathways.[42] Additionally, this new pathway will provide much needed predictability to innovators and device manufacturers, and possibly encourage further investment in medical device startups.[43]

The MCIT Final Rule becomes effective on March 15, 2021.[44]

1 "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary": Final Rule" Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2987; "CMS unleashes innovation to ensure our nation's seniors have access to the latest advancements" Centers for Medicare & Medicaid Services, January 12, 2021, https://www.cms.gov/newsroom/press-releases/cms-unleashes-innovation-ensure-our-nations-seniors-have-access-latest-advancements (Accessed 1/22/21).
2 "Executive Order 13890 of October 3, 2019: Protecting and Improving Medicare for Our Nation's Seniors" Federal Registrar, Vol. 84, No. 195 (October 8, 2019), p. 53573.
3 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2988.
4 *Ibid*, p. 2987- 2988.
5 This list describes the pathways that are most often available to medical devices, but is not comprehensive of all available Medicare Coverage Pathways.
6 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2989.
7 *Ibid*.
8 *Ibid*.
9 *Ibid*.
10 Centers for Medicare & Medicaid Services (CMS), January 12, 2021.
11 *Ibid*.
12 *Ibid*.
13 *Ibid*.
14 *Ibid*.
15 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2988.
16 *Ibid*.
17 *Ibid*.
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19 "Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff" U.S. Food & Drug Administration (FDA), December 18, 2018, https://www.fda.gov/media/108135/download (Accessed 1/22/21).
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21 *See* "FDA Breakthrough Devices Program nears 300 designations" By Susan Kelly, MedTechDive, May 27, 2020, https://www.medtechdive.com/news/fda-breakthrough-devices-orteq-archerdx-terumo-thermedical-helius-photopharmics/578562/ (Accessed 1/25/21).
22 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2988.
23 Kelly, May 27, 2020.
24 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 3009.
25 *Ibid*, p. 2991.
26 Centers for Medicare & Medicaid Services (CMS), January 12, 2021.
27 *Ibid*.
28 *Ibid*.
29 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2993.
30 *Ibid*.
31 "Proposed Medicare Coverage of Innovative Technology (CMS-3372-P)" Centers for Medicare & Medicaid Services (CMS), August 31, 2020 https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p (Accessed 1/22/21).
32 *Ibid*.
33 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2993.
34 Social Security Act (SSA) § 1862(a)(1)(A).
35 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2993.
36 *Ibid*.
37 *Ibid*.
38 *Ibid*.
39 *Ibid*.
40 "Re: CMS-3372-P: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" National Venture Capital Association (NVCA), November 2, 2020, available at: https://nvca.org/wp-content/uploads/2020/11/NVCA-CMS-Comments-re-MCIT-Pathway-11022020.pdf (Accessed 1/25/21); "Advanced Medical Technology Association Issues Public Comment on Centers for Medicare & Medicaid Services Proposed Rule" InsuranceNewsNet, November 23, 2020, https://insurancenewsnet.com/oarticle/advanced-medical-technology-association-issues-public-comment-on-centers-for-medicare-medicaid-services-proposed-rule (Accessed 1/25/21); "Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' [CMS–3372–P]" Medical Device Manufacturers Association (MDMA), November 2, 2020, available at: https://cdn.ymaws.com/www.medicaldevices.org/resource/resmgr/reimbursement_wg_docs/2020-11-2--_MDMA_to_CMS_Re-_.pdf (Accessed 1/25/21).
41 *Ibid*.
42 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2989.
43 National Venture Capital Association (NVCA), November 2, 2020.
44 Federal Registrar, Vol. 86, No. 9 (January 14, 2021), p. 2987.

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