Alliance for Regenerative Medicine

VIA ELECTRONIC DELIVERY

November 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3372–P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary' (CMS-3372-P)

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS'/the Agency's) proposed rule, entitled "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"" (the "Proposed Rule").[1] Specifically, ARM appreciates CMS' proposed new coverage pathway and expanded regulatory definition of "Reasonable and Necessary" for breakthrough devices as new tools to expedite coverage to innovative technologies.

ARM is the leading international advocacy organization dedicated to realizing the promise of regenerative medicines and advanced therapies. ARM promotes legislative, regulatory and reimbursement initiatives to advance this innovative and transformative sector, which includes cell therapies, gene therapies and tissue-based therapies. Early products to market have demonstrated profound, durable, and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options. Hundreds of additional product candidates contribute to a robust pipeline of potentially life-changing regenerative medicines and advanced therapies. In its 11-year history, ARM has become the voice of the sector, representing the interests of 360+ members worldwide, including small and large companies, academic research institutions, major medical centers, and patient groups.

ARM estimates there are 1,001 regenerative medicine and advanced therapy developers worldwide sponsoring 1,078 clinical trials across dozens of indications, including oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[2]

[1] 85 Fed. Reg. 54,327 (September 1, 2020).
[2] https://alliancerm.org/sector-report/h1-2020-report/

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ARM believes this new pathway and definition could improve Medicare beneficiary access to innovative device technologies but urges the Agency to not apply either proposal to drugs and biologicals ("biologicals"). As detailed below, ARM agrees with the reasoning behind these new proposals as applied to breakthrough devices but does not believe that the same market conditions necessitating the MCIT pathway apply for biologicals. In particular, the Social Security Act ("SSA") provides clear guidance to CMS regarding coverage and payment for newly approved FDA therapies, such that a new coverage pathway is not warranted. In fact, should the Agency establish the MCIT pathway for biologicals, ARM is concerned that access will actually be hampered based upon ARM's experience during the NCD for CAR-T therapies. Specifically, changes in the traditional coverage approach for drugs and biologicals can hamper access early and incorrectly as was the case during the NCD process. ARM know that before the NCD was final, some Medicare providers mistakenly believed CAR T-cell therapies were not covered for Medicare beneficiaries, delaying if not effectively denying equitable access for these beneficiaries. As such, ARM is concerned that a new and mostly unnecessary coverage pathway would not help, rather hinder access to newly approved FDA biologicals.

I. Executive Summary:

- The Executive Order did not mention biologicals indicating the Administration does not view coverage as a barrier to access.
- The SSA provides a clear path for coverage and payment for FDA approved biologicals.
- If applied to biologicals, the MCIT pathway will create confusion in the marketplace regarding coverage and delay access.
- CMS Should Not Codify the Proposed definition of "reasonable and necessary," however, if the definition of "reasonable and necessary" is finalized, ARM urges CMS to use commercial coverage polices only to expand coverage and not narrow coverage of biologicals.
- ARM urges CMS to remind Medicare Advantage plans of their obligation to cover items and services covered by Fee-for-Service Medicare regardless of MCIT participation.
- CMS should expand MCIT to certain other benefit categories.

II. The Executive Order Does Not Mention Biologicals Indicating the Administration Does Not Currently View Coverage as a Barrier to Access

On October 3, 2020, the Administration issued an Executive Order directing CMS to propose regulatory and sub-regulatory changes to the Medicare program to streamline "the approval, coverage, and coding process so that innovative products are brought to market faster, and so that such products, including breakthrough medical devices and advances in telehealth services and similar technologies, are appropriately reimbursed and widely available,

consistent with the principles of patient safety, market-based policies, and value for patients."[3] As CMS states the Executive Order ("EO") explicitly includes making coverage of breakthrough medical devices widely available and to clarify the application of coverage standards to these FDA approved technologies.[4] CMS asks for comments as to whether the EO should also apply to biologicals since they were not mentioned in the EO.[5] ARM believes that because the EO specifically mentions only breakthrough devices, biologicals should not be included. Biologicals can also receive breakthrough designation such that if the Administration believes that there currently is a coverage issue for breakthrough biologicals it would have also mentioned them in the EO. As such, ARM urges CMS to only include breakthrough devices at this time when applying the new MCIT pathway.

III. The Social Security Act Provides A Clear Coverage Process to CMS Regarding Newly Approved Biologicals

CMS states "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" as an improvement over CMS' current tools that provide coverage for this class of devices.[6] ARM agrees with CMS as it relates to devices but does not believe MCIT pathway is necessary to provide immediate coverage for biologicals beginning as of the date of FDA approval because the SSA provides a clear definition for drugs and biologicals for CMS to follow when determining coverage, regardless of FDA designation.[7] This statutory provision has guided CMS' coverage since its inception to provide immediate access to newly approved FDA biologicals. ARM believes the current construct serves Medicare beneficiaries well in that they have access to newly approved biologicals without the MCIT pathway. As discussed, however, in other ARM comment letters and those of other stakeholders, timely access to biologicals in specific sites of care and under the Medicaid program are the issues, which are outside the scope of this proposal. Therefore, based on current law and the scope of the MCIT proposal ARM does not believe CMS should extend the MCIT pathway to biologicals.

In contrast to the predictable coverage, coding and payment processes for many biologicals, access to breakthrough devices is a much more timely and opaque process. Timely access to new technologies involves more than just Medicare coverage upon FDA market authorization. In addition to coverage, billing codes and transparent and publicly available payment rates give providers confidence that the item and/or services provided will be paid. Without these other key functions related to the technology, market access is typically significantly delayed.

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[3] E.O. 13890 of Oct 3, 2019, Section 6. https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors

[4] 85 Fed. Reg. 54,328.

[5] Id. at 54,331.

[6] 85 Fed. Reg. 54,330.

[7] SSA §1861(t).

For breakthrough and all other devices, FDA market authorization typically starts a long journey over many years towards obtaining a permanent billing code and predictable payment rates by the Medicare Administrative Contractors ("MAC"). As CMS knows, obtaining a Category III code, then coverage and payment for that code at the local level often takes years absorbing and consuming many breakthrough device manufacturer resources. Simultaneous to obtaining coverage and payment at the local level, the long process towards obtaining a permanent Category I code with a national price begins. These lengthy processes can take up to five years and are usually the real reasons behind delayed access to breakthrough devices, much more so than coverage. As such, ARM urges to finalize the MCIT pathway for breakthrough devices and to CMS to clarify how it will establish a unique billing code and transparent reimbursement at launch under the MCIT program. This clarity will dramatically help beneficiary access to breakthrough devices, which already occurs for biologicals.

IV. If Applied to Biologicals, the MCIT Pathway Will Create Confusion in the Market Regarding Coverage and Delay Access.

As discussed in previous comments[8], current cell, gene, regenerative, and immunotherapies are the first in a wave of new and exciting advanced therapies and technologies that are the next frontier in the fight against some of humankind's most devastating diseases and disorders. ARM is currently tracking the outcomes of hundreds of ongoing clinical trials using these technologies in a variety of stages of cancer and cancer types. In addition, ARM tracks hundreds of other clinical trials exploring the power of the immune system and believes that the new and promising technologies of our members provides the possibility that future treatments for many types of cancer at its many stages could be durable and curative.

As stated above, ARM supports CMS' efforts to create the MCIT pathway for breakthrough devices. The lack of immediate coverage for these devices are well understood by the healthcare community including, providers, physicians, investors, and beneficiaries. As such, the MCIT pathway will likely be well understood and received over current options for breakthrough devices.

However, as mentioned above, based on ARM's experience with the CAR T NCD, ARM believes that the opposite will be true for biologicals in that access may be delayed due to a change in process. Specifically, many in the healthcare community know that because of current law, biologicals are overwhelmingly covered upon FDA approval such that the introduction of the MCIT will likely create confusion amongst physicians and providers regarding coverage. ARM is concerned that the introduction of a new MCIT pathway to biologicals will likely have the opposite impact to that of breakthrough devices in that prescribers may now not believe the biological to be covered. Therefore, in order to maintain consistent and appropriate access to newly FDA approved biologicals, ARM urges CMS to not apply the MCIT pathway to biologicals.

[8] Link to IPPS comments

V. CMS Should Not Codify the Proposed Definition of "Reasonable and Necessary, However, if the Definition of "Reasonable and Necessary" is Finalized, ARM Urges CMS To Use Commercial Coverage Polices Only to Expand Coverage and Not Narrow Coverage of Biologicals.

ARM does not support CMS' proposal to codify a definition of "reasonable and necessary" because the current flexibility provided by the definition in the Program Integrity Manual ("PIM") provides appropriate balance between regulatory flexibility and stakeholder guidance regarding satisfying the "reasonable and necessary" criteria. There is a long history behind the meaning of the term reasonable and necessary in the Medicare statute and ARM does not believe codifying the language contained in Medicare's sub regulatory guidance is needed in order to achieve the result CMS seeks. The longstanding language in Medicare's PIM is well-known and understood by stakeholders including CMS and industry. Retaining this definition in sub-regulatory guidance will allow CMS to have greater flexibility in interpreting whether an item or service is reasonable and necessary for Medicare beneficiaries.

If, however, CMS does codify the current Program Integrity Manual (PIM) definition of "reasonable and necessary" with a modification that would permit the Agency to reference commercial insurance coverage polices when making a coverage determination, ARM urges the Agency to only do so to expand coverage.[9] CMS reasons that by considering commercial health insurer coverage policies, the Agency would be expanding its knowledge base by bringing together the "expertise of private payers and CMS."[10] ARM appreciates CMS' goal to bring more experts to the coverage decision, but urges CMS to do so only if it leads to coverage.

ARM is concerned that including commercial payers could compromise the integrity of the overall coverage process if it can lead to non-coverage or reduced coverage. Commercial payers have much different economic pressures driving their decisions, have many fewer legal obligations and, as stated by CMS typically serve a much different patient population. Commercial insurers do not have the same transparency standards into the evidence reviewed as CMS and use cost-effectiveness and other similar analytic tools that are outside the coverage process of CMS. Plus, many commercial payers clearly rely on CMS' coverage polices when determining their own. As such, if a commercial payer policy or polices are used to deny Medicare coverage it will likely be seen by beneficiaries and others as self-serving by the commercial plan to avoid following a CMS policy and/or satisfy other pressures that are not at all related to serving Medicare beneficiaries.

ARM believes that CMS recognizes the appearance of these conflicts when it states "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

[9] 85 Fed. Reg. 54,331.
[10] 85 Fed. Reg. 54,332.

individuals are clinically relevant."[11] It seems from this statement that the Agency will only use commercial polices to expand coverage. Therefore, should CMS finalize this additional option for meeting the "reasonable and necessary" requirement, the Agency should remove any appearance of conflict and clarify that it can only be used to expand coverage and not limit coverage.

Finally, in the event that CMS adopts a new definition of "reasonable and necessary" that incorporates reference to commercial coverage for biologicals, ARM is hopeful that CMS will further engage with ARM and other stakeholders to determine, specifically, how to best reference and apply commercial policies to foster expanded coverage decisions.

VI. CMS Must Remind Medicare Advantage of Their Obligation to Cover Items and Services Covered by Fee-for-Service Medicare

CMS states that it will 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. ARM agrees with that approach but urges CMS to remind Medicare Advantage plans that items and services that are covered by Medicare Parts A and B under the Fee-for-Service ("FFS") program must also be covered by Medicare Advantage plans. In other words, Medicare Advantage plans must cover breakthrough devices participating in the MCIT program, just like all other items and services covered under FFS Medicare.[12]

VII. CMS Should Expand the MCIT To Certain Other Benefit Categories

CMS' proposal focuses on establishing in regulations the factors it has historically used in making ''reasonable and necessary'' determinations under section 1862(a)(1)(A) of the SSA. This section explains that Medicare payment may be made under Medicare Parts A or 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."[13] Thus, with some exceptions, section 1862(a)(1)(A) of the SSA requires that an item or service be ''reasonable and necessary'' to be covered by Medicare. This coverage occurs presuming the device also fits within Medicare benefit category that diagnoses or treats a disease and is not otherwise excluded from coverage by statute (that is, the Medicare statute does not allow for coverage of the particular device).[14] ARM appreciates this approach, and as mentioned above, urges CMS to finalize the MCIT pathway for breakthrough devices subsequently deemed reasonable and necessary under section 1862(a)(1)(A)of the SSA.

ARM, however, urges CMS to expand the MCIT pathway to certain other benefit categories created by Congress and further detailed in, but not limited to, Section 1861 of the

[11] 85 Fed. Reg. 54,322.
[12] 42 C.F.R. § 422.101.
[13] 85 Fed. Reg. 54,329.
[14] Id.

SSA. In creating the MCIT pathway, CMS aims to address many of the challenges that breakthrough devices have in reaching Medicare beneficiaries upon FDA approval. ARM knows that these same access challenges, although for different reasons, also exist for technologies that are covered by Medicare via other congressionally defined benefit categories. For many of the new technologies covered under different benefit categories, National Coverage Determinations ("NCD") are required before national coverage is established. For example, any new screening test that serves the same function as that which is detailed in the statute but uses a different method of screening must go through the NCD process before it is nationally covered. This process seems to be the one of the problems that breakthrough devices have upon FDA approval, which is delayed access to the technology by Medicare beneficiaries upon FDA approval. To resolve this access delay, ARM urges CMS to expand the MCIT pathway to those other benefit categories established by Congress. Finally, by expanding the MCIT pathway to screening tests, CMS could incentivize the creation of many more preventative and screening services that will ultimately help detect and treat Medicare beneficiaries leading to hopefully better outcomes.

VIII. Conclusion

ARM is confident that meaningful improvements in clinical outcomes and cost reduction can be accomplished through regenerative medicine technologies. ARM believes that the field of regenerative medicine has the potential to heal people and bend the health cost curve toward lower long-term costs and higher quality outcomes. This trend is already evidenced by several approved and marketed first-generation regenerative medicine products that are demonstrating both clinical and cost reduction value. Specifically, by reducing hospital care, the need for physician, clinical and professional services, nursing, and home healthcare, we could substantially reduce overall healthcare expenses.

ARM believes that is critical for CMS to develop and implement policies and programs that support the use of new technologies and therefore supports CMS' proposals to expedite access to breakthrough devices via the MCIT pathway. ARM, however, believes that this pathway is unnecessary and not warranted for biologicals and should therefore not be applied to these therapies.

We thank CMS for its many proposals and statements in the Proposed Rule and look forward to working with CMS to establish policies that promote appropriate access to new and innovative therapies in both the near term and long. Please free to contact me at rfalb@alliancerm.org with questions.

Sincerely,

Robert J. Falb
Director, U.S. Policy and Advocacy