Summary of Breakthrough Pathway Proposed Rule

On August 31, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited proposed rule on "Medicare Coverage of Innovative Technologies." The proposed rule would make significant changes to streamline Medicare coverage for FDA-designated breakthrough technologies that have market authorization.

Automatic Coverage for Breakthrough Technologies: The proposed rule would create a new, voluntary Medicare Coverage of Innovative Technologies (MCIT) pathway that would provide immediate, national Medicare coverage of any FDA-market authorized breakthrough device if the device meets certain criteria. This automatic coverage would begin on the date of FDA-market authorization and would last for four years, after which time coverage would be determined through existing processes (national or local coverage determinations, or claim-by-claim adjudication).

- **Retroactivity**: The MCIT program would apply to breakthrough devices that received FDA authorization not more than two calendar years prior to the effective date of the final rule and thereafter. For devices approved prior to the effective date of the rule, the 4-year timeframe of coverage from date of market authorization would remain in effect, meaning the coverage policy may only apply for the remaining time of the 4-year period.

- **Exclusions**: Automatic coverage under MCIT would exclude products that do not fall within the Part A or B coverage benefit (for example, certain digital or wearable technologies) or for product categories that are specifically excluded from Medicare coverage, such as hearing aids. CMS also is excluding drugs and biologics.

- **Application to Devices and Diagnostics:** CMS states in the preamble that MCIT coverage would be limited to devices only, and exclude diagnostics, biologics and drugs. However, elsewhere in the proposed rule, CMS states that automatic coverage under the MCIT pathway would apply to breakthrough technologies, which are defined as providing for "more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions," and for which "no approved or cleared alternatives exist or which offers significant advantages over existing approved or cleared alternatives." Additionally, CMS specifically calls out breakthrough diagnostic tests in their press release and factsheet. CMS is seeking comments on whether the MCIT pathway should apply to diagnostics.

- **Coverage with Evidence Development**: The proposed rule does not require additional data development or clinical studies during the four-year coverage period. However, CMS is soliciting comment on whether it should require manufacturers to provide data about outcomes or to enter into clinical studies, similar to CMS's Coverage with Evidence Development (CED) paradigm. The proposed rule would not impact FDA-required post-market data collection, and manufacturers would be encouraged to develop clinical evidence that may be needed for one of the other coverage pathways after the MCIT pathway ends, or evidence to better inform the clinical community about the new technology.

Continued Coverage after MCIT and MAC Coverage: CMS proposes that, at the end of the four-year MCIT coverage period, three different scenarios are possible:

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).

CMS states that manufacturers interested in a NCD should submit a request during the third year of MCIT coverage to allow for sufficient time for NCD development, and the agency seeks comment on whether CMS should open a national coverage analysis if a MAC has not already

issued an LCD for a breakthrough device within 6 months of the expiration date of the 4-year MCIT period.

Proposals Defining "Reasonable and Necessary": The proposed rule would define the term "reasonable and necessary" under Sec. 1862(a)(1)(A) of the Social Security Act, by codifying language in the current Medicare Program Integrity Manual. Further, innovative devices covered via the MCIT pathway would be deemed to be reasonable and necessary *per se*.

CMS proposes to define reasonable and necessary as:

1. safe and effective;
2. not experimental or investigational and
3. appropriate, 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.

In addition to the above criteria, CMS separately proposes to consider whether a device is "appropriate" under (3) above based on commercial health insurers' coverage policies. The Industry associations are still reviewing how the coverage policies for commercial insurers could be applied, but CMS states that they could be used to expand and/or *narrow* Medicare coverage.