

Section 1.1: Home Infusion Therapy Services

INTRODUCTION TO HOME INFUSION THERAPY SERVICES

Section 5012 of the 21st Century Cures Act (Cures Act) established a new home infusion therapy benefit program. Medicare Part B began covering home infusion therapy services for eligible home infusion therapy suppliers January 2019.

Home infusion therapy services under the new benefit program has requirements of participation. The patient must be under the care of an applicable provider, defined as a physician, nurse practitioner, or physician's assistant, and have a physician-established individualized plan of care (POC) that is periodically reviewed by the physician. The POC must include furnishing a home infusion drug or biological that is administered intravenously or subcutaneously for an administration period of 15 minutes or more, through a pump that is an item of DME.

Professional services are included under the new benefit program, for provision of infusion therapy by a qualified clinician furnished in accordance with a POC and performed in a patient's home, defined as a place of residence used as the home of an individual. Training, education, remote monitoring, and other monitoring services are additional requirements.

Temporary transitional payments are available now for providers that qualify as eligible home infusion therapy suppliers, under temporary transitional regulations. Eligible home infusion therapy suppliers have been defined as existing suppliers enrolled in Medicare as pharmacies, that provide external infusion pumps and external infusion pump supplies, and maintain all pharmacy licensure requirements in the state in which the applicable infusion drugs and biologicals will be administered.

Complete implementation of the new Medicare home infusion therapy benefit program will become effective January 1, 2021. Temporary transitional regulations are effective January 1, 2019 through December 31, 2020 (as established by Section 50401 of the Bipartisan Budget Act (BBA) of 2018), to begin limited implementation of the program while providing time for necessary provider accreditation and further program development.

All home infusion therapy suppliers are required to be accredited by an accrediting organization (AO) no later than January 1, 2021, as designated by the Secretary of Health and Human Services in accordance with the regulations set forth in the 21st Century Cures Act. The accreditation requirements apply to both new participants, as well as providers that are deemed eligible home infusion therapy suppliers at this time.

The home infusion therapy supplier is not required to directly provide all parts of the program under the new benefit beginning in 2021. The provider is allowed to subcontract with a pharmacy, physician, other qualified supplier and/or provider of medical services, in order to meet program requirements. Under the temporary transitional regulations, eligible home infusion therapy suppliers are only allowed to subcontract the required professional services.

Limitations on allowed infusion drugs and biologicals were established, and additional medications will be included throughout the program development. Infusions through insulin pump systems and Self-Administered Drugs (SAD) and biologicals listed on the CMS drug exclusion list are currently not included.

The 21st Century Cures Act anticipated relationships between eligible home infusion therapy suppliers and home health agencies during the transitional period, allowing subcontracting of field staff to perform home services. Professional services can be billed separate from, or on the same claim as the DME, supplies, and infusion medications. Claims will be processed through the DME Medicare Administrative Contractors (MACs) during the temporary period from January 1, 2019 through December 31, 2020.

The temporary period will be replaced by the complete Medicare home infusion therapy benefit program, effective January 1, 2021. Providers that plan to supply home infusion therapy services after January 1, 2021 must be accredited and enrolled as Medicare home infusion therapy suppliers. Accreditation standards will be released in 2020, then pharmacies, DME suppliers, and other providers of medical services such as physician offices and home health agencies, can apply for accreditation to become a home infusion therapy supplier for the new benefit program.

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