DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850

DATE: December 9, 2024

TO: Medicare Advantage Organizations
Section1876 Cost Plans
Programs of All-Inclusive Care for the Elderly

SUBJECT: Medicare Advantage Coverage of Part B Drug - Qalsody

CMS has observed that some Medicare Advantage (MA) plans are inappropriately denying Medicare Part B drug coverage for the U.S. Food & Drug Administration (FDA) approved drug Qalsody (tofersen), used for the treatment of amyotrophic lateral sclerosis (ALS), by classifying it as "experimental and investigational" for all indications. The FDA granted accelerated approval to Qalsody on April 25, 2023, for the treatment of ALS in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene[1].

In Medicare Part B, use of drugs or biologicals must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals approved for marketing by the FDA are considered safe and effective when used for indications specified on the labeling and CMS does not make a distinction between drugs that are marketed under an accelerated FDA-approval versus a traditional FDA-approval. Medicare Part B may pay for the use of an FDA-approved drug or biological if it was administered on or after the date of the FDA's approval, it is reasonable and necessary for the individual patient, and all other applicable coverage requirements are met (Section 50 of the Medicare Benefit Policy Manual, Chapter 15). Section 1852(a)(1) of the Social Security Act requires MA plans to provide coverage of all drugs and services covered under Medicare Parts A and B (with limited exceptions not applicable here)[2], and therefore, it is impermissible for MA plans to have a blanket coverage policy that excludes Qalsody from Medicare Part B coverage by considering it "experimental and investigational."

In accordance with § 422.101(b)(6), MA plans may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Currently, there are no applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs) that provide additional coverage requirements for the use of Qalsody for ALS and MA plans may create internal coverage criteria under the rules at § 422.101(b)(6). However, MA plans must make individual medical necessity determinations as outlined at § 422.101(c)[3]; based on the circumstances of each specific individual, including the

[1] https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-treatment-amyotrophic-lateral-sclerosis-associated-mutation-sod1-gene
[2] See also 42 CFR § 422.101(a) and (b).
[3] MA organizations must make medical necessity determinations based on all of the following:
(A) Coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not specified in § 422.101(b) or (c).
(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.
(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.
(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

patient's medical history, physician recommendations, and clinical notes. Any policies that result in an automatic denial of coverage for a covered Part B item or service, without considering the individual patient's medical history, would violate § 422.101(c).

We expect that all MA plans that currently classify Qalsody as experimental and investigational for the treatment of ALS in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene will immediately discontinue use of those coverage policies and comply with the rules outlined at § 422.101 on requirements relating to basic benefits. Further, we expect MA plans to expeditiously contact enrollees that were inappropriately denied coverage of Qalsody based on its classification as experimental and investigational to inform them that coverage policies for Qalsody have changed.