Select High Cost, Orphan, and Accelerated Approval Drugs

This data table provides interim coverage information for a list of select drugs, including high cost drugs, orphan drugs, and other drugs approved under a Food and Drug Administration (FDA) accelerated approval pathway. These drugs are covered for FDA-approved indications when medically necessary. Information about a drug's FDA-approved indication(s) can be found on the FDA website. Specific interim billing and coverage information for each drug can be found in the table below. These drugs and the billing or coverage of ancillary services related to these drugs are subject to all existing ForwardHealth coverage and billing policy, which may be found in the ForwardHealth Online Handbook on the ForwardHealth Portal.

If a drug listed below has established drug-specific clinical criteria, refer to the Services Requiring Prior Authorization chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook on the Portal for information about the clinical criteria and directions for submitting prior authorization (PA) requests.

If a drug listed below requires PA to support that use is for an FDA-approved indication and is medically necessary as defined by Wis. Admin. Code § DHS 101.03(96m) but does not have drug-specific clinical criteria, PA requests must be submitted using Section VII (Clinical Information for Other Drug Requests) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016), and the Prior Authorization Request Form (PA/RF), F-11018 (05/13). Medical records (e.g., chart notes, laboratory values) must be submitted along with the PA request to support that use is both medically necessary and for an FDA-approved indication. The drug must be prescribed in a dose and manner consistent with FDA-approved product labeling.

For specific questions about the billing or coverage of high cost, orphan, and accelerated approval drugs listed in this data table, providers may contact Provider Services at 800-947-9627 or email DHSOrphanDrugs@dhs.wisconsin.gov.

Note: The information contained in this data table is subject to change, and it is the provider's responsibility to remain up-to-date with the information included in this data table.

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CRYSVITA burosumab-twza	o Crysvita requires PA to support that use is for an FDA-approved indication and is medically necessary. o If a PA request for Crysvita is approved, Crysvita will be covered under the pharmacy benefit. o To bill ForwardHealth for Crysvita, pharmacy providers should submit a pharmacy noncompound drug claim.
ENDARI L-glutamine oral powder	o Endari requires PA; established clinical criteria for Endari can be found in the Online Handbook on the Portal. o If a PA request for Endari is approved, Endari will be covered under the pharmacy benefit. o To bill ForwardHealth for Endari, pharmacy providers should submit a pharmacy noncompound drug claim.

EXONDYS 51 eteplirsen	o Exondys 51 requires PA to support that use is for an FDA-approved indication and is medically necessary. o If a PA request for Exondys 51 is approved, Exondys 51 will be covered under the pharmacy benefit. o To bill ForwardHealth for Exondys 51, pharmacy providers should submit a pharmacy noncompound drug claim.
KYMRIAH tisagenlecleucel	o Kymriah does not require PA. o Kymriah will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., National Comprehensive Cancer Network [NCCN] guidelines). o Kymriah will be covered under the pharmacy benefit. o To bill ForwardHealth for Kymriah, pharmacy providers should submit a pharmacy noncompound drug claim.
LUXTURNA voretigene neparvovec-rzyl	o Luxturna requires PA; established clinical criteria for Luxturna can be found in the Online Handbook on the Portal. o If a PA request for Luxturna is approved, Luxturna will be covered under the pharmacy benefit. o To bill ForwardHealth for Luxturna, pharmacy providers should submit a pharmacy noncompound drug claim.
MEPSEVII vestronidase alfa-vjbk	o Mepsevii requires PA to support that use is for an FDA-approved indication and is medically necessary. o If a PA request for Mepsevii is approved, Mepsevii will be covered under the pharmacy benefit. o To bill ForwardHealth for Mepsevii, pharmacy providers should submit a pharmacy noncompound drug claim.
PALYNZIQ pegvaliase-pqpz	o Palynziq requires PA; established clinical criteria for Palynziq can be found in the Online Handbook on the Portal. o If a PA request for Palynziq is approved, Palynziq will be covered under the pharmacy benefit. o To bill ForwardHealth for Palynziq, pharmacy providers should submit a pharmacy noncompound drug claim.
SPINRAZA nusinersen	o Spinraza requires PA; established clinical criteria for Spinraza can be found in the Online Handbook on the Portal. o If a PA request for Spinraza is approved, Spinraza will be covered under the pharmacy benefit. o To bill ForwardHealth for Spinraza, pharmacy providers should submit a pharmacy noncompound drug claim.

YESCARTA axicabtagene ciloleucel	o Yescarta does not require PA. o Yescarta will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines). o Yescarta will be covered under the pharmacy benefit. o To bill ForwardHealth for Yescarta, pharmacy providers should submit a pharmacy noncompound drug claim.

Note: Pharmacy providers who receive Medicaid reimbursement for select high cost, orphan, and accelerated approval drugs may be subject to audit at any time. Pharmacy providers are required to retain relevant documentation supporting adherence to ForwardHealth program requirements and produce it for and/or submit it to ForwardHealth upon request. ForwardHealth may deny or recoup payment for services that fail to meet program requirements.