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.

Effective: 08/01/2023 (Revised: 08/03/2023)

ABECMA idecabtagene	○ Abecma does not require PA. ○ Abecma 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). ○ Abecma will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Abecma, pharmacy providers should submit a pharmacy noncompound drug claim.

AMONDYS 45 casimersen	○ Amondys 45 requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Amondys 45 is approved, Amondys 45 will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Amondys 45, pharmacy providers should submit a pharmacy noncompound drug claim.
BREYANZI lisocabtagene maraleucel	○ Breyanzi does not require PA. ○ Breyanzi 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). ○ Breyanzi will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Breyanzi, pharmacy providers should submit a pharmacy noncompound drug claim.
BRINEURA cerliponase	○ Brineura does not require PA. ○ Brineura 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). ○ Brineura will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Brineura, pharmacy providers should ○ submit a pharmacy noncompound drug claim.
CARVYKTI ciltacabtagene	○ Carvykti does not require PA. ○ Carvykti 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). ○ Carvykti will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Carvykti, pharmacy providers should submit a pharmacy noncompound drug claim.
CEREZYME imiglucerase	○ Cerezyme does not require PA. ○ Cerezyme 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). ○ Cerezyme will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Cerezyme, pharmacy providers should submit a pharmacy noncompound drug claim.
CRYSVITA burosumab-twza	○ Crysvita requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Crysvita is approved, Crysvita will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Crysvita, pharmacy providers should submit a pharmacy noncompound drug claim.

ELEVIDYS delandistrogene moxeparvovec-rokl	○ Elevidys requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Elevidys is approved, Elevidys will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Elevidys, pharmacy providers should submit a pharmacy noncompound drug claim.
EXONDYS 51 eteplirsen	○ Exondys 51 requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Exondys 51 is approved, Exondys 51 will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Exondys 51, pharmacy providers should submit a pharmacy noncompound drug claim.
GAMIFANT emapalumab-lzsg	○ Gamifant requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Gamifant is approved, Gamifant will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Gamifant, pharmacy providers should submit a pharmacy noncompound drug claim.
HEMGENIX etranacogene dezaparvovec - drlb	○ Hemgenix requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ A PA/DGA form Section VII must be submitted with the following clinical documentation and medical records to support the member's medical condition and outline the member's current treatment plan. • Hemgenix must be prescribed by a hematologist at a dose of 2 x 1013 genome copies (gc) per kg of body weight. • Member has been diagnosed with Hemophilia B (congenital Factor IX deficiency) and is 18 years of age or older. • Member must currently be treated with Factor IX prophylaxis therapy. • Member must have a current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. • Prescriber must include documentation of Factor IX inhibitor titer testing. In case of a positive test result for human Factor IX inhibitors, perform a re-test within approximately 2 weeks. If both the initial test and re-test results are positive, PA for HEMGENIX will not be approved. • Prescriber must include documentation of liver health assessments including, ALT, AST, ALP, total bilirubin, hepatic ultrasound, and hepatic elastography. If the member has radiological liver abnormalities and/or sustained liver enzyme elevations, documentation of a consultation with a hepatologist to assess eligibility for

	HEMGENIX will be required. o If a PA request for Hemgenix is approved, Hemgenix will be covered under the pharmacy benefit. o To bill ForwardHealth for Hemgenix, pharmacy providers should submit a pharmacy noncompound drug claim. o Hemgenix will be reimbursed separately from physician and clinical services associated with the administration of Hemgenix. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Hemgenix is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for the Hemgenix that has been administered to a member. If Hemgenix has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Hemgenix that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
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., 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.

ONPATTRO patisiran	○ Onpattro does not require PA. ○ Onpattro 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). ○ Onpattro will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Onpattro, pharmacy providers should submit a pharmacy noncompound drug claim.
OXERVATE cenegermin	○ Oxervate does not require PA. ○ Oxervate 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). ○ Oxervate will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Oxervate, pharmacy providers should submit a pharmacy noncompound drug claim.
ROCTAVIAN valoctocogene roxaparvovec-rvox	○ Roctavian requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ A PA/DGA form Section VII must be submitted with the following clinical documentation and medical records to support the member's medical condition and outline the member's current treatment plan. • Roctavian must be prescribed by a hematologist at a dose of 6 x 1013 vector genomes (vg) per kg of body weight. • Member has been diagnosed with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) and is 18 years of age or older. • Prescriber must include documentation of testing for pre-existing antibodies to AAV5 using the FDA approved companion diagnostic. If the companion diagnostic test is positive for antibodies to AAV5, PA for Roctavian will not be approved. • Prescriber must include documentation of liver health assessments including, ALT, AST, GGT, ALP, total bilirubin, INR, hepatic ultrasound and elastography, or laboratory assessments for liver fibrosis. If the member has radiological liver abnormalities and/or sustained liver enzyme elevations, documentation of a consultation with a hepatologist to assess eligibility for Roctavian will be required. ○ If a PA request for Roctavian is approved, Roctavian will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Roctavian, pharmacy providers should submit a pharmacy noncompound drug claim. ○ Roctavian will be reimbursed separately from physician and clinical services associated with the administration of Roctavian. The pharmacy provider is required to establish a delivery process

	with the prescriber to ensure that the physician-administered Roctavian is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for the Roctavian that has been administered to a member. If Roctavian has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Roctavian that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
RUZURGI amifampridine	o Ruzurgi requires PA to support that use is for an FDA-approved indication and is medically necessary. o If a PA request for Ruzurgi is approved, Ruzurgi will be covered under the pharmacy benefit. o To bill ForwardHealth for Ruzurgi, 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.
TECARTUS brexucabtagene	o Tecartus does not require PA. o Tecartus 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 Tecartus will be covered under the pharmacy benefit. o To bill ForwardHealth for Tecartus, pharmacy providers should submit a pharmacy noncompound drug claim.
VILTEPSO viltolarsen	o Viltepso requires PA to support that use is for an FDA-approved indication and is medically necessary. o If a PA request for Viltepso is approved, Viltepso will be covered under the pharmacy benefit. o To bill ForwardHealth for Viltepso, pharmacy providers should submit a pharmacy noncompound drug claim.
VIMIZIM elosulfase alfa	o Vimizim does not require PA. o Vimizim 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 Vimizim will be covered under the pharmacy benefit. o To bill ForwardHealth for Vimizim, pharmacy providers should submit a pharmacy noncompound drug claim.

VYJUVEK beremagene geperpavec-svdt	○ Vyjuvek requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ A PA/DGA form Section VII must be submitted with the following clinical documentation and medical records to support the member's medical condition and outline the member's current treatment plan. • Vyjuvek must be prescribed by a dermatologist or wound care specialist. • Member has been diagnosed with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene and is 6 months of age or older. • Prescriber must include documentation of at least one cutaneous wound that is appropriate to be treated with Vyjuvek and confirm that the wound does not appear to be infected. • Prescriber must include documentation of the size of the wound area (s) to be treated and confirm the calculated dose of Vyjuvek will not exceed the recommended maximum weekly dose. • Prescriber must include documentation that the member's treatment plan includes the appropriate administration of Vyjuvek by a healthcare provider and the wound dressing care required for treatment with Vyjuvek. • Prescriber must include documentation that the member's treatment plan addresses the requirement for Vyjuvek to be properly prepared at a pharmacy for administration to the member's wound(s) within 8 hours of mixing of the Vyjuvek gel with the Vyjuvek biological suspension. ○ If a PA request for Vyjuvek is approved, Vyjuvek will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Vyjuvek, pharmacy providers should submit a pharmacy noncompound drug claim. ○ Vyjuvek will be reimbursed separately from physician and clinical services associated with the administration of Vyjuvek. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that Vyjuvek is delivered directly to the prescriber, an agent of the prescriber, or a healthcare provider designated to administer Vyjuvek to the member. Pharmacy providers may only submit a claim to ForwardHealth for the Vyjuvek that has been administered to a member. If Vyjuvek has been dispensed for a member but the dose is not administered to the member, the prescriber or healthcare provider designated to administer Vyjuvek to the member is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Vyjuvek that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.

VYONDYS 53 golodirsen	o Vyondys 53 requires PA to support that use is for an FDA-approved indication and is medically necessary. o If a PA request for Vyondys 53 is approved, Vyondys 53 will be covered under the pharmacy benefit. o To bill ForwardHealth for Vyondys 53, 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.
ZOLGENSMA onasemnogene abeparvovec-xioi	o Zolgensma requires PA; established clinical criteria for Zolgensma can be found in the Online Handbook on the Portal. o If a PA request for Zolgensma is approved, Zolgensma will be covered under the pharmacy benefit. o To bill ForwardHealth for Zolgensma, 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.