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: 12/01/2024

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.
CASGEVY exagamglogene autotemcel	○ Casgevy 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. **<u>Clinical Criteria for β-thalassemia</u>** • Casgevy must be prescribed and administered by a physician and treatment center with expertise in treating β-thalassemia with Casgevy. • Casgevy must be prescribed at a minimum recommended dose of 3.0×10^6 CD34+ cells/kg of body weight. • The member has B-thalassemia, which requires regular RBC transfusions. The member has a history of transfusions for the past

	two years of at least 100 mL/kg/year of packed RBCs or with eight or more transfusions of packed RBCs per year. • The member's age is consistent with the FDA-approved product labeling for Casgevy. • The member will undergo hematopoietic stem cell (HSC) mobilization, apheresis, and myeloablative conditioning. The prescriber must confirm the member has been evaluated for renal and hepatic impairment and HSC transplantation is appropriate for the member. • The member must have full myeloablative conditioning administered before infusion of Casgevy. Full myeloablative conditioning must be administered between 48 hours and 7 days before infusion of Casgevy. • The prescriber will provide documentation of completed negative screening for infectious diseases including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human Tlymphotropic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines before collection of cells for manufacturing. • Standard procedures for patient management after HSC transplantation should be followed after Casgevy infusion. • The prescriber must manage other concomitant medications (as applicable) consistent with FDA product labeling. • The member must not take disease modifying therapies (e.g. crizanlizumab, hydroxyurea, L-glutamine, voxelotor) for at least 8 weeks prior to mobilization. • The member must not take iron chelation therapy at least 7 days prior to myeloablative conditioning. The member must not take non-myelosuppressive iron chelators for at least 3 months and myelosuppressive iron chelators for at least 6 months after Casgevy infusion. **Clinical Criteria for Sickle Cell Disease** • Casgevy must be prescribed and administered by a physician and treatment center with expertise in treating sickle cell disease with Casgevy. • Casgevy must be prescribed at a minimum recommended dose of 3 × 10^6 CD34+ cells per kg of body weight. • **At least one** of the following is true: ▪ The member has experienced an unsatisfactory therapeutic response with hydroxyurea. ▪ The member has experienced a clinically significant adverse drug reaction with hydroxyurea.

	▪ There is a clinically significant drug interaction between another drug(s) the member is taking and hydroxyurea. ▪ The member has a medical condition(s) that prevents the use of hydroxyurea. • The member has sickle cell disease (SCD) with a history of severe vaso-occlusive events (VOEs). The member must have at least 4 severe vaso-occlusive events (VOEs) within the previous 2 years. The severe VOEs must include one or more of the following: ▪ Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDS]) or red blood cell RBC transfusions. ▪ Acute chest syndrome. ▪ Priapism lasting >2 hours and requiring a visit to a medical facility. ▪ Splenic sequestration. • The member's age is consistent with the FDA-approved product labeling for Casgevy. • The member will undergo hematopoietic stem cell (HSC) mobilization, apheresis, and myeloablative conditioning. The prescriber must confirm the member has been evaluated for renal and hepatic impairment and HSC transplantation is appropriate for the member. • The member must have full myeloablative conditioning administered before infusion of Casgevy. Full myeloablative conditioning must be administered between 48 hours and 7 days before infusion of Casgevy. • The prescriber will provide documentation of completed negative screening for infectious diseases including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines before collection of cells for manufacturing. • Standard procedures for patient management after HSC transplantation should be followed after Casgevy infusion. • The prescriber must manage other concomitant medications (as applicable) consistent with FDA product labeling. • Granulocyte-Colony Stimulating Factor (G-CSF) must not be used prior to or with mobilization and conditioning. • The member must not take disease modifying therapies for sickle cell disease (e.g. crizanlizumab, hydroxyurea, L-glutamine, voxelotor) for at least 8 weeks prior to mobilization.

	• The member must not take iron chelation therapy at least 7 days prior to myeloablative conditioning. The member must not take non-myelosuppressive iron chelators for at least 3 months and myelosuppressive iron chelators for at least 6 months after Casgevy infusion. PA requests for Casgevy **will not** be approved for Casgevy if the member has any of the following conditions: • Advanced liver disease: (e.g. alanine transaminases > 3 times upper limit of normal; direct bilirubin value > 2.5 times upper limit of normal; baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal; cirrhosis; bridging fibrosis/cirrhosis; or active hepatitis) • History of untreated Moyamoya disease, or presence of Moyamoya disease that in the opinion of the Casgevy prescriber puts the member at risk of bleeding. • Prior or current malignancy or myeloproliferative disorder or significant immunodeficiency disorder. • Prior allogenic or autologous hematopoietic stem cell (HSC) transplant. o If a PA request for Casgevy is approved, Casgevy will be covered under the pharmacy benefit. o To bill ForwardHealth for Casgevy, pharmacy providers should submit a pharmacy noncompound drug claim. o Casgevy will be reimbursed separately from physician and clinical services associated with the administration of Casgevy. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Casgevy is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for the Casgevy that has been administered to a member. If Casgevy 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 Casgevy that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
CEREZYME imiglucerase	o Cerezyme does not require PA. o 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). o Cerezyme will be covered under the pharmacy benefit. o 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.
ELAPRASE idursulfase	○ Elaprase does not require PA. ○ Elaprase 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). ○ Elaprase will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Elaprase, 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 ; established clinical criteria for Hemgenix can be found in the Online Handbook on the Portal.. ○ If a PA request for Hemgenix is approved, Hemgenix will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Hemgenix, pharmacy providers should submit a pharmacy noncompound drug claim.
KYMRIAH tisagenlecleucel	○ Kymriah does not require PA. ○ 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). ○ Kymriah will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Kymriah, pharmacy providers should submit a pharmacy noncompound drug claim.

LUXTURNA voretigene neparvovec- rzyl	○ Luxturna requires PA; established clinical criteria for Luxturna can be found in the Online Handbook on the Portal. ○ If a PA request for Luxturna is approved, Luxturna will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Luxturna, pharmacy providers should submit a pharmacy noncompound drug claim.
LYFGENIA lovotibeglogene autotemcel	○ Lyfgenia 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. • Lyfgenia must be prescribed at a minimum recommended dose of 3×10^6 CD34+ cells/kg of body weight. • **At least one** of the following is true: ▪ The member has experienced an unsatisfactory therapeutic response with hydroxyurea. ▪ The member has experienced a clinically significant adverse drug reaction with hydroxyurea. ▪ There is a clinically significant drug interaction between another drug(s) the member is taking and hydroxyurea. ▪ The member has a medical condition(s) that prevents the use of hydroxyurea. • The member has sickle cell disease (SCD) with a history of severe vaso-occlusive events (VOEs). The member must have at least 4 severe vaso-occlusive events (VOEs) within the previous 2 years. The severe VOEs must include one or more of the following: ▪ Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDS]) or red blood cell RBC transfusions. ▪ Acute chest syndrome. ▪ Priapism lasting >2 hours and requiring a visit to a medical facility. ▪ Splenic sequestration. • The member's age is consistent with the FDA-approved product labeling for Lyfgenia. • The member will undergo hematopoietic stem cell (HSC) mobilization, apheresis, and myeloablative conditioning. The prescriber must confirm the member has been evaluated for renal and hepatic impairment and HSC transplantation is appropriate for the member. • The member must have full myeloablative conditioning administered before infusion of Lyfgenia. Full myeloablative

	conditioning must be administered a minimum of 48 hours before infusion of Lyfgenia. • The prescriber will provide documentation of completed negative screening for infectious diseases including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines before collection of cells for manufacturing. • Standard procedures for patient management after HSC transplantation should be followed after Lyfgenia infusion. • The prescriber must manage other concomitant medications (as applicable) consistent with FDA product labeling. • Granulocyte-Colony Stimulating Factor (G-CSF) must not be used prior to or with mobilization and conditioning. G-CSF is not recommended for at least 21 days after Lyfgenia infusion. • The member must not take prophylactic HIV anti-retroviral medications for at least 1 month prior to mobilization and until all cycles of apheresis are completed. Adjust time appropriately for long-acting anti-retroviral medications. • The member must not take hydroxyurea at least 2 months prior to mobilization and 2 days prior to conditioning and will not resume until all cycles of apheresis are completed. • The member must not take disease modifying therapies for sickle cell disease (e.g., crizanlizumab, L-glutamine, voxelotor) for at least 2 months prior to mobilization. • The member must not take erythropoietin for at least 2 months prior to mobilization. • The member must no take iron chelation therapy at least 7 days prior to mobilization and conditioning. If the member takes iron chelation after apheresis the member must discontinue iron chelation at least 7 days prior to myeloablative conditioning. Myelosuppressive iron chelators are not recommended for 6 months after Lyfgenia infusion. PA requests for Lyfgenia **will not** be approved if the member has any of the following conditions: • Advanced liver disease: (e.g. alanine transaminases > 3 times upper limit of normal; direct bilirubin value > 2.5 times upper limit of normal; baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal; cirrhosis; bridging fibrosis/cirrhosis; or active hepatitis) • History of untreated Moyamoya disease, or presence of Moyamoya disease that in the opinion of the Lyfgenia prescriber puts the member at risk of bleeding.

	• Prior or current malignancy or myeloproliferative disorder or significant immunodeficiency disorder. • Prior allogenic or autologous hematopoietic stem cell (HSC) transplant. • More than two alpha-globin gene deletions. o If a PA request for Lyfgenia is approved, Lyfgenia will be covered under the pharmacy benefit. o To bill ForwardHealth for Lyfgenia, pharmacy providers should submit a pharmacy noncompound drug claim. o Lyfgenia will be reimbursed separately from physician and clinical services associated with the administration of Lyfgenia. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Lyfgenia is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for the Lyfgenia that has been administered to a member. If Lyfgenia 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 Lyfgenia that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
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	o Onpattro does not require PA. o 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). o Onpattro will be covered under the pharmacy benefit. o To bill ForwardHealth for Onpattro, pharmacy providers should submit a pharmacy noncompound drug claim.
OXERVATE cenegermin	o Oxervate does not require PA. o 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). o Oxervate will be covered under the pharmacy benefit. o To bill ForwardHealth for Oxervate, pharmacy providers should submit a pharmacy noncompound drug claim.

ROCTAVIAN valoctocogene roxaparvovec-rvox	○ Roctavian requires PA ; established clinical criteria for Roctavian can be found in the Online Handbook on the Portal.. ○ 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.
RUZURGI amifampridine	○ Ruzurgi requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Ruzurgi is approved, Ruzurgi will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Ruzurgi, pharmacy providers should submit a pharmacy noncompound drug claim.
SKYSONA elivaldogene	○ Skysona requires PA; established clinical criteria for Skysona can be found in the Online Handbook on the Portal. ○ If a PA request for Skysona is approved, Skysona will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Skysona, pharmacy providers should submit a pharmacy noncompound drug claim.
SPINRAZA nusinersen	○ Spinraza requires PA; established clinical criteria for Spinraza can be found in the Online Handbook on the Portal. ○ If a PA request for Spinraza is approved, Spinraza will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Spinraza, pharmacy providers should submit a pharmacy noncompound drug claim.
TECARTUS brexucabtagene	○ Tecartus does not require PA. ○ 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). ○ Tecartus will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Tecartus, pharmacy providers should submit a pharmacy noncompound drug claim.
TECELRA afamitresgene	○ Tecelra does not require PA. ○ Tecelra 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). ○ Tecelra will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Tecelra, 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	o Vyjuvek requires PA ; established clinical criteria for Vyjuvek can be found in the Online Handbook on the Portal. o If a PA request for Vyjuvek is approved, Vyjuvek will be covered under the pharmacy benefit. o To bill ForwardHealth for Vyjuvek, pharmacy providers should submit a pharmacy noncompound drug claim.
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.

ZYNTEGLO betibeglogene	○ Zynteglo requires PA; established clinical criteria for Zynteglo can be found in the Online Handbook on the Portal. ○ If a PA request for Zynteglo is approved, Zynteglo will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Zynteglo, 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.