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 <u>Services</u> <u>Requiring Prior Authorization</u> 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 <u>DHSOrphanDrugs@dhs.wisconsin.gov</u>.

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 1/1/20	022
ABECMA	• Abecma does not require PA.	
idecabtagene	• 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 relevan	ıt
	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.	

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AMONDYS 45	• Amondys 45 requires PA to support that use is for an FDA-approved
casimersen	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	 Breyanzi does not require PA.
lisocabtagene	• Breyanzi will only be reimbursed when used for an FDA-approved
maraleucel	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.
CRYSVITA	• Crysvita requires PA to support that use is for an FDA-approved
burosumab-twza	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.
DOJOLVI	• Dojolvi requires PA to support that use is for an FDA-approved
triheptanoin	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.
	• Member has a confirmed diagnosis of a long-chain fatty acid
	oxidation disorder.
	• Dietary assessment and plan which includes member's
	height, weight and estimated total daily caloric intake.
	• Complete dietary treatment plan, including a copy of the
	prescription order for Dojolvi. The treatment plan must
	include the target daily dosage of Dojolvi as a percentage of
	total daily caloric intake.
	Note: Dojolvi is prescribed in mls and the recommended
	target daily dosage is up to 35% of the member's total daily
	caloric intake divided into at least four doses.
	• If a PA request for Dojolvi is approved, Dojolvi will be covered
	under the pharmacy benefit.
	• To bill ForwardHealth for Dojolvi, providers should submit a
	pharmacy noncompound drug claim.
EVRYSDI	• Evrysdi requires PA; established clinical criteria for Evrysdi can be
risdiplam	found in the Online Handbook on the Portal.
	• If a PA request for Evrysdi is approved, Evrysdi will be covered
	under the pharmacy benefit.
	• To bill ForwardHealth for Evrysdi, pharmacy providers should
	submit a pharmacy noncompound drug claim.

EXONDYS 51	• Exondys 51 requires PA to support that use is for an FDA-approved
eteplirsen	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.
FIRDAPSE	• Firdapse requires PA to support that use is for an FDA-approved
amifampridine	indication and is medically necessary.
	• If a PA request for Firdapse is approved, Firdapse will be covered
	under the pharmacy benefit.
	• To bill ForwardHealth for Firdapse, pharmacy providers should
	submit a pharmacy noncompound drug claim.
GAMIFANT	• Gamifant requires PA to support that use is for an FDA-approved
emapalumab-lzsg	indication and is medically necessary.
1 0	 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.
JYNARQUE	
tolvaptan	• Jynarque requires PA; established clinical criteria for Jynarque can be found in the Online Handbook on the Portal.
torvaptan	
	• If a PA request for Jynarque is approved, Jynarque will be covered under the pharmacy benefit.
	 To bill ForwardHealth for Jynarque, pharmacy providers should submit a pharmacy noncompound drug claim.
KYMRIAH tisagenlecleucel	• Kymriah does not require PA.
tisagemeeteueet	• 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
ΙΙΨΤΙΌΝΙΑ	submit a pharmacy noncompound drug claim.
LUXTURNA voretigene neparvovec-	• Luxturna requires PA; established clinical criteria for Luxturna can
rzyl	be found in the Online Handbook on the Portal.
J -	• 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.
MEPSEVII	• Mepsevii requires PA to support that use is for an FDA-approved
vestronidase alfa-vjbk	indication and is medically necessary.
	• If a PA request for Mepsevii is approved, Mepsevii will be covered
	under the pharmacy benefit.
	• To bill ForwardHealth for Mepsevii, pharmacy providers should
	submit a pharmacy noncompound drug claim.

ONPATTRO	• Onpattro does not require PA.
patisiran	
patisiran	• 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.
ORLADEYO	• Orladeyo requires PA; established clinical criteria for Orladeyo can
berotralstat	be found in the Online Handbook on the Portal.
	• If a PA request for Orladeyo is approved, Orladeyo will be covered
	under the pharmacy benefit.
	• To bill ForwardHealth for Orladeyo, pharmacy providers should
	submit a pharmacy noncompound drug claim.
OXERVATE	• Oxervate does not require PA.
cenegermin	• 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.
PALYNZIQ	 Palynziq requires PA; established clinical criteria for Palynziq can
pegvaliase-pqpz	be found in the Online Handbook on the Portal.
r o a r ir	 If a PA request for Palynziq is approved, Palynziq will be covered
	under the pharmacy benefit.
	 To bill ForwardHealth for Palynziq, 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
annampriume	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.
SPINRAZA	• Spinraza requires PA; established clinical criteria for Spinraza can
nusinersen	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.
TAKHZYRO	• Takhzyro requires PA; established clinical criteria for Takhzyro can
lanadelumab-flyo	be found in the Online Handbook on the Portal.
-	• If a PA request for Takhzyro is approved, Takhzyro will be covered
	under the pharmacy benefit.
	 To bill ForwardHealth for Takhzyro, pharmacy providers should
	submit a pharmacy noncompound drug claim.
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TECARTUS	• Tecartus does not require PA.
brexucabtagene	• 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.
TEGSEDI	• Tegsedi does not require PA.
inotersen	• Tegsedi 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).
	• Tegsedi will be covered under the pharmacy benefit.
	• To bill ForwardHealth for Tegsedi, pharmacy providers should
	submit a pharmacy noncompound drug claim.
VILTEPSO	• Viltepso requires PA to support that use is for an FDA-approved
viltolarsen	indication and is medically necessary.
	 If a PA request for Viltepso is approved, Viltepso will be covered
	under the pharmacy benefit.
	 To bill ForwardHealth for Viltepso, pharmacy providers should
	submit a pharmacy noncompound drug claim.
VYONDYS 53	 Vyondys 53 requires PA to support that use is for an FDA-approved
golodirsen	indication and is medically necessary.
Solounsen	
	• If a PA request for Vyondys 53 is approved, Vyondys 53 will be covered under the pharmacy benefit.
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	• To bill ForwardHealth for Vyondys 53, pharmacy providers should
VECCADTA	submit a pharmacy noncompound drug claim.
YESCARTA	• Yescarta does not require PA.
axicabtagene ciloleucel	• 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).
	• Yescarta will be covered under the pharmacy benefit.
	• To bill ForwardHealth for Yescarta, pharmacy providers should
	submit a pharmacy noncompound drug claim.
ZOKINVY	• Zokinvy requires PA to support that use is for an FDA-approved
lonafarnib	indication and is medically necessary.
	• If a PA request for Zokinvy is approved, Zokinvy will be covered
	under the pharmacy benefit.
	• To bill ForwardHealth for Zokinvy, pharmacy providers should
	submit a pharmacy noncompound drug claim.

ZOLGENSMA onasemnogene abeparvovec-xioi	 Zolgensma requires PA; established clinical criteria for Zolgensma can be found in the Online Handbook on the Portal. If a PA request for Zolgensma is approved, Zolgensma will be covered under the pharmacy benefit. To bill ForwardHealth for Zolgensma, pharmacy providers should submit a pharmacy noncompound drug claim.
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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.