

FDA approvals and expedited pathways used - new molecular entities

Published: Nov 1, 2020 - **State & Federal** / Medicare

Anthem Blue Cross and Blue Shield (Anthem) reviews the activities of the FDA's approval of drugs and biologics on a regular basis to understand the potential effects for both our providers and members.

The FDA approves new drugs/biologics using various pathways of approval. Recent studies on the effectiveness of drugs/biologics going through these different FDA pathways illustrates the importance of clinicians being aware of the clinical data behind a drug or biologic approval in making informed decisions.

Here is a list of the approval pathways the FDA uses for drugs/biologics:

- **Standard Review:** The Standard Review process follows well-established paths to make sure drugs/biologics are safe and effective when they reach the public. From concept to approval and beyond, FDA performs these steps: reviews research data and information about drugs and biologics before they become available to the public, watches for problems once drugs and biologics are available to the public, monitors drug/biologic information and advertising, and protects drug/biologic quality. [Click here to learn more about the Standard Review process.](#)
- **Fast Track:** Fast Track is a process designed to facilitate the development and expedite the review of drugs/biologics to treat serious conditions and fill an unmet medical need. [Click here to learn more about the Fast Track process.](#)
- **Priority Review:** A Priority Review designation means FDA's goal is to take action on an application within six months. [Click here to learn more about the Priority Review process.](#)
- **Breakthrough Therapy:** A process designed to expedite the development and review of drugs/biologics that may demonstrate substantial improvement over available therapy. [Click here to learn more about the Breakthrough Therapy process.](#)
- **Orphan Review:** Orphan Review is the evaluation and development of drugs/biologics that demonstrate promise for the diagnosis and/or treatment of rare diseases or

conditions. [Click here to learn more about the Orphan Review process.](#)

- **Accelerated Approval:** These regulations allowed drugs/biologics for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint. [Click here to learn more about the Accelerated Approval process.](#)

New molecular entities approvals — January to August 2020

Certain drugs/biologics are classified as new molecular entities (NMEs) for purposes of FDA review. Many of these products contain active ingredients that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product; these products frequently provide important new therapies for patients.

Anthem reviews the FDA-approved NMEs on a regular basis. To facilitate the decision-making process, we are providing a list of NMEs approved from January to August 2020, along with the FDA approval pathway utilized.

Generic name	Trade name	Standard Review	Fast Track	Priority Review	Break-through Therapy	Orphan Review	Accelerated Approval
Abametapir	Xeglyze	X					
Amisulpride	Barhemys	X					
Avapritinib	Ayvakit		X	X	X	X	
Belantamab mafodotin	Blenrep			X	X	X	X
Bempedoic acid	Nexletol	X					
Brexucabtagene autoleucel	Tecartus			X	X	X	X
Capmatinib	Tabrecta			X	X	X	X
Decitabine/ cedazuridine	Inqovi			X		X	
Eptinezumab-jjmr	Vyepti	X					
Fostemsavir	Rukobia		X	X	X		
Inebilizumab	Uplizna	X			X	X	
Isatuximab	Sarclisa	X				X	
Lurbinectedin	Zepzelca			X		X	X
Nifurtimox	Lampit			X		X	X
Oliceridine	Olinvyk	X	X				
Opicapone	Ongentys	X					
Osilodrostat	Isturisa	X				X	

Generic name	Trade name	Standard Review	Fast Track	Priority Review	Break-through Therapy	Orphan Review	Accelerated Approval
Ozanimod	Zeposia	X					
Peanut (Arachis hypogaea) allergen powder-dnfp	Palforzia	X	X		X		
Pemigatinib	Pemazyre			X	X	X	X
Remimazolam	Byfavo	X					
Rimegepant	Nurtec ODT			X			
Risdiplam	Evrysdi		X	X	X	X	
Ripretinib	Qinlock		X	X	X	X	
Sacituzumab-hziy	Trodelvy		X	X	X	X	X
Selpercatinib	Retevmo			X	X	X	X
Selumetinib	Koselugo		X	X	X	X	
Tafasitamab	Monjuvi	X	X		X	X	X
Tazemetostat	Tazverik			X		X	X
Teprotumumab-trbw	Tepezza		X	X	X	X	
Triheptanoin	Dojolvi	X	X			X	
Tucatinib	Tukysa		X	X	X	X	
Viltolarsen	Viltepso		X	X		X	X

Source: [fda.gov](https://www.fda.gov)

URL: <https://providernews.anthem.com/wisconsin/article/fda-approvals-and-expedited-pathways-used-new-molecular-entities-3>

Featured In:

November 2020 Anthem Provider News - Indiana, November 2020 Anthem Provider News - Kentucky, November 2020 Anthem Provider News - Missouri, November 2020 Anthem Provider News - Ohio, November 2020 Anthem Provider News - Wisconsin

Anthem Blue Cross and Blue Shield is the trade name of: In Colorado Rocky Mountain Hospital and Medical Service, Inc. HMO products underwritten by HMO Colorado, Inc. In Connecticut: Anthem Health Plans, Inc. In Georgia: Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. In Indiana: Anthem Insurance Companies, Inc. In Kentucky: Anthem Health Plans of Kentucky, Inc. In Maine: Anthem Health Plans of Maine, Inc. In Missouri (excluding 30 counties in the Kansas City area): RightCHOICE® Managed Care, Inc. (RIT), Healthy Alliance® Life Insurance Company (HALIC), and HMO Missouri, Inc. RIT and certain affiliates administer non-HMO benefits underwritten by HALIC and HMO benefits underwritten by HMO Missouri, Inc. RIT and certain affiliates only provide administrative services for self-funded plans and do not underwrite benefits. In Nevada: Rocky Mountain Hospital and Medical Service, Inc. HMO products underwritten by HMO Colorado, Inc. dba HMO Nevada. In New Hampshire: Anthem Health Plans of New Hampshire, Inc. HMO plans are administered by Anthem Health Plans of New Hampshire, Inc. and underwritten by Matthew Thornton Health Plan, Inc. In Ohio: Community Insurance Company. In Virginia: Anthem Health Plans of Virginia, Inc. trades as Anthem Blue Cross and Blue Shield in Virginia, and its service area is all of Virginia except for the City of Fairfax, the Town of Vienna, and the area east of State Route 123. In Wisconsin: Blue Cross Blue Shield of Wisconsin (BCBSWI), which underwrites or administers the PPO and indemnity policies and underwrites the out of network benefits in POS policies offered by CompCare or WCIC; CompCare Health Services Insurance Corporation (CompCare) underwrites or administers the HMO policies and Wisconsin Collaborative Insurance Company (WCIC) underwrites or administers Well Priority HMO or POS policies. Independent licensees of the Blue Cross and Blue Shield Association. Anthem is a registered trademark of Anthem Insurance Companies, Inc. The Blue Cross and Blue Shield names and symbols are registered marks of the Blue Cross and Blue Shield Association. Use of the Anthem websites constitutes your agreement with our Terms of Use.
