FDA approvals and expedited pathways used -- new molecular entities

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

The FDA approves new drugs and biologics using various pathways. Recent studies on the effectiveness of drugs and biologics going through 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. Follow this **link** 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. Follow this **link** 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. Follow this **link** to learn more about the priority review process.
- **Breakthrough therapy** — This process is designed to expedite the development and review of drugs/biologics which may demonstrate substantial improvement over available therapy. Follow this **link** to learn more about the breakthrough therapy review process.
- **Orphan review** — This refers to the review of drugs that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. Follow this **link** to learn more

about the orphan drug 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. To learn more about the accelerated approval process, follow this **link**.

New molecular entities approvals: January 2020 through 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.

Note: This information has no impact on our standard prior authorization/precertification process.

Generic name	Trade name	Standard review	Fast track	Priority	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		
Ozanimod	Zeposia	X						
Peanut (Arachis hypogaea) allergen powder-dnfp	Palforzia	X	X		X			

Generic name	Trade name	Standard review	Fast track	Priority	Break-through therapy	Orphan review	Accelerated approval	
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: **www.fda.gov**

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