

FDA approvals and expedited pathways used - New Molecular Entities (NMEs)

ARTICLE ATTACHMENT

New Molecular Entities Approvals: January – 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	Approval Date	Indication
Abametapir	Xeglyze	X						7/24/2020	Head lice
Amisulpride	Barhemys	X						2/26/2020	Postoperative nausea and vomiting
Avapritinib	Ayvakit		X	X	X	X		1/9/2020	PDGFRa exon 18 mutant gastrointestinal stromal tumor
Belantamab mafodotin	Blenrep			X	X	X	X	8/05/2020	Multiple myeloma
Bempedoic acid	Nexletol	X						2/21/2020	Dyslipidemia
Brexucabtagene autoleucel	Tecartus			X	X	X	X	7/24/2020	Mantle cell lymphoma
Capmatinib	Tabrecta			X	X	X	X	5/6/2020	Non-small cell lung cancer (NSCLC)
Decitabine/cedazuridine	Inqovi			X		X		7/07/2020	Myelodysplastic syndromes
Eptinezumab-jjmr	Vyepti	X						2/21/2020	Migraine prevention
Fostemsavir	Rukobia		X	X	X			7/02/2020	Human immunodeficiency virus (HIV) treatment
Inebilizumab	Uplizna	X			X	X		6/11/2020	Neuromyelitis optica spectrum disorder
Isatuximab	Sarclisa	X				X		3/2/2020	Multiple myeloma
Lurbinectedin	Zepzelca			X		X	X	6/15/2020	NSCLC
Nifurtimox	Lampit			X		X	X	8/06/2020	Chagas disease
Oliceridine	Olinvyk	X	X					8/07/2020	Moderate to severe acute pain
Opicapone	Ongentys	X						4/24/2020	Parkinson's disease
Osilodrostat	Isturisa	X				X		3/6/2020	Cushing's disease
Ozanimod	Zeposia	X						3/25/2020	Multiple sclerosis
Peanut (Arachis hypogaea) allergen powder-dnfp	Palforzia	X	X		X			1/31/2020	Peanut allergy
Pemigatinib	Pemazyre			X	X	X	X	4/17/2020	Cholangiocarcinoma
Remimazolam	Byfavo	X						7/02/2020	Sedation for procedures

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Rimegepant	Nurtec ODT			X				2/27/2020	Migraine treatment
Risdiplam	Evrysdi		X	X	X	X		8/07/2020	Spinal muscular atrophy
Ripretinib	Qinlock		X	X	X	X		5/15/2020	Gastrointestinal stromal tumor
Sacituzumab-hziy	Trodelyv		X	X	X	X	X	4/22/2020	Triple negative breast cancer
Selpercatinib	Retevmo			X	X	X	X	5/8/2020	NSCLC and thyroid cancers
Selumetinib	Koselugo		X	X	X	X		4/10/2020	Neurofibromatosis type 1
Tafasitamab	Monjuvi	X	X		X	X	X	7/31/2020	Large B-cell lymphoma
Tazemetostat	Tazverik			X		X	X	1/23/2020	Epithelioid sarcoma
Teprotumumab-trbw	Tepezza		X	X	X	X		1/21/2020	Thyroid eye disease
Triheptanoin	Dojolvi	X	X					6/30/2020	Long-chain fatty acid oxidation disorders
Tucatinib	Tukysa		X	X	X	X		4/17/2020	Breast cancer
Viltolarsen	Viltepso		X	X		X	X	8/12/2020	Duchenne muscular dystrophy

Source: www.fda.gov

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