

New FDA 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 help facilitate the decision-making process, see the following 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						7/24/20	Head lice
Amisulpride	Barhemys	X						2/26/20	Postoperative nausea and vomiting
Avapritinib	Ayvakit		X	X	X	X		1/9/20	PDGFRa exon 18 mutant gastrointestinal stromal tumor
Belantamab mafodotin	Blenrep			X	X	X	X	8/5/20	Multiple myeloma
Bempedoic acid	Nexletol	X						2/21/20	Dyslipidemia
Brexucabtagene autoleucel	Tecartus			X	X	X	X	7/24/20	Mantle cell lymphoma
Capmatinib	Tabrecta			X	X	X	X	5/6/20	Non-small cell lung cancer (NSCLC)
Decitabine/ cedazuridine	Inqovi			X		X		7/7/20	Myelodysplastic syndromes
Eptinezumab-jjmr	Vyepti	X						2/21/20	Migraine prevention
Fostemsavir	Rukobia		X	X	X			7/2/20	Human immunodeficiency virus (HIV) treatment
Inebilizumab	Uplizna	X			X	X		6/11/20	Neuromyelitis optica spectrum disorder
Isatuximab	Sarclisa	X				X		3/2/20	Multiple myeloma
Lurbinectedin	Zepzelca			X		X	X	6/15/20	NSCLC

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Nifurtimox	Lampit			X		X	X	8/6/20	Chagas disease
Oliceridine	Olinvyk	X	X					8/7/20	Moderate to severe acute pain
Opicapone	Ongentys	X						4/24/20	Parkinson's disease
Osilodrostat	Isturisa	X				X		3/6/20	Cushing's disease
Ozanimod	Zeposia	X						3/25/20	Multiple sclerosis
Peanut (Arachis hypogaea) allergen powder-dnfp	Palforzia	X	X		X			1/31/20	Peanut allergy
Pemigatinib	Pemazyre			X	X	X	X	4/17/20	Cholangiocarcinoma
Remimazolam	Byfavo	X						7/2/20	Sedation for procedures
Rimegepant	Nurtec ODT			X				2/27/20	Migraine treatment
Risdiplam	Evrysdi		X	X	X	X		8/7/20	Spinal muscular atrophy
Ripretinib	Qinlock		X	X	X	X		5/15/20	Gastrointestinal stromal tumor
Sacituzumab-hziy	Trodelvy		X	X	X	X	X	4/22/20	Triple negative breast cancer
Selpercatinib	Retevmo			X	X	X	X	5/8/20	NSCLC and thyroid cancers
Selumetinib	Koselugo		X	X	X	X		4/10/20	Neurofibromatosis type 1
Tafasitamab	Monjuvi	X	X		X	X	X	7/31/20	Large B-cell lymphoma
Tazemetostat	Tazverik			X		X	X	1/23/20	Epithelioid sarcoma
Teprotumumab-trbw	Tepezza		X	X	X	X		1/21/20	Thyroid eye disease
Triheptanoin	Dojolvi	X	X			X		6/30/20	Long-chain fatty acid oxidation disorders
Tucatinib	Tukysa		X	X	X	X		4/17/20	Breast cancer
Viltolarsen	Viltepso		X	X		X	X	8/12/20	Duchenne muscular dystrophy

Source: www.fda.gov

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