



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	Approval date	Indication
Abametapir	Xeglyze	X						July 24, 2020	Head lice
Amisulpride	Barhemys	X						February 26, 2020	Postoperative nausea and vomiting
Avapritinib	Ayvakit		X	X	X	X		January 9, 2020	PDGFRa exon 18 mutant gastrointestinal stromal tumor
Belantamab mafodotin	Blenrep			X	X	X	X	August 5, 2020	Multiple myeloma
Bempedoic acid	Nexletol	X						February 21, 2020	Dyslipidemia
Brexucabtagene autoleucel	Tecartus			X	X	X	X	July 24, 2020	Mantle cell lymphoma
Capmatinib	Tabrecta			X	X	X	X	May 6, 2020	Non-small cell lung cancer (NSCLC)
Decitabine/cedazuridine	Inqovi			X		X		July 7, 2020	Myelodysplastic syndromes
Eptinezumab-jjmr	Vyepiti	X						February 21, 2020	Migraine prevention
Fostemsavir	Rukobia		X	X	X			July 2, 2020	HIV treatment
Inebilizumab	Uplizna	X			X	X		June 11, 2020	Neuromyelitis optica spectrum disorder
Isatuximab	Sarclisa	X				X		March 2, 2020	Multiple myeloma
Lurbinectedin	Zepzelca			X		X	X	June 15, 2020	NSCLC
Nifurtimox	Lampit			X		X	X	August 6, 2020	Chagas disease
Oliceridine	Olinvyk	X	X					August 7, 2020	Moderate to severe acute pain
Opicapone	Ongentys	X						April 24, 2020	Parkinson's disease
Osilodrostat	Isturisa	X				X		March 6, 2020	Cushing's disease
Ozanimod	Zeposia	X						March 25, 2020	Multiple sclerosis
Peanut (Arachis hypogaea)	Palforzia	X	X		X			January 31, 2020	Peanut allergy

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allergen powder-dnfp									
Pemigatinib	Pemazyre			X	X	X	X	April 17, 2020	Cholangiocarcinoma
Remimazolam	Byfavo	X						April 2, 2020	Sedation for procedures
Rimegepant	Nurtec ODT			X				February 27, 2020	Migraine treatment
Risdiplam	Evryssi		X	X	X	X		August 7, 2020	Spinal muscular atrophy
Ripretinib	Qinlock		X	X	X	X		May 15, 2020	Gastrointestinal stromal tumor
Sacituzumab-hziy	Trodelvy		X	X	X	X	X	April 22, 2020	Triple negative breast cancer
Selpercatinib	Retevmo			X	X	X	X	May 8, 2020	NSCLC and thyroid cancers
Selumetinib	Koselugo		X	X	X	X		April 10, 2020	Neurofibromatosis type 1
Tafasitamab	Monjuvi	X	X		X	X	X	July 31, 2020	Large B-cell lymphoma
Tazemetostat	Tazverik			X		X	X	January 23, 2020	Epithelioid sarcoma
Teprotumumab-trbw	Tepezza		X	X	X	X		January 21, 2020	Thyroid eye disease
Triheptanoin	Dojolvi	X	X			X		June 30, 2020	Long-chain fatty acid oxidation disorders
Tucatinib	Tukysa		X	X	X	X		April 17, 2020	Breast cancer
Viltolarsen	Viltepso		X	X		X	X	August 12, 2020	Duchenne muscular dystrophy

Source: www.fda.gov