

Drug	Approved for	Type	Original Approval	Pediatric Approval	Indication
Mercaptopurine	Adults/Peds	Chemo	9/11/1953	***	ALL
Methotrexate	Adults/Peds	Chemo	8/10/1959	***	ALL, meningeal leukemia, osteosarcoma, non-Hodgkin lymphoma
Cyclophosphamide	Adults/Peds	Chemo	11/16/1959	***	Leukemia, lymphoma, NBL, retinoblastoma
Vincristine	Adults/Peds	Chemo	7/10/1963	***	ALL, lymphoma, Wilms, rhabdomyosarcoma, NBL
Dactinomycin	Adults/Peds		12/10/1964	***	Ewing Sarcoma, sarcoma botryoides
Vinblastine	Adults/Peds	Chemo	11/5/1965	***	Histiocytosis, testicular germ cell carcinoma, Hodgkin lymphoma
Thioguanine	Adults/Peds	Chemo	1/18/1966	***	Acute non-lymphocytic leukemia
Cytarabine	Adults/Peds	Chemo	6/17/1969	***	Acute non-lymphocytic leukemia
Procarbozine	Adults/Peds	Chemo	7/22/1969	***	Hodgkin lymphoma
Doxorubicin	Adults/Peds	Chemo	8/7/1974	***	Wilms tumor, NBL, soft tissue sarcoma, Hodgkin lymphoma, other lymphomas, ALL, AML
Lomustine	Adults/Peds	Chemo	8/4/1976	***	Brain Tumors, Hodgkin lymphoma
L-Asparaginase	Adults/Peds	NME*	1/10/1978	***	Leukemia
Daunorubicin	Adults/Peds	Chemo	12/19/1979	***	ALL
Teniposide	Pediatrics	NME*	7/14/1992	10/1/2002	Refractory ALL
PEG-Asparaginase	Peds/AYA	NME*	2/2/1994	***	ALL
Tretinoin	Adults/Peds	Chemo	11/22/1995	***	APML
*FDAMA, enacted Nov. 21, 1997, amended the Federal Food, Drug, and Cosmetic Act relating to the regulation of food, drugs, devices, and biological products					
Gemtuzumab	Adults/Peds	MAB**	5/17/2000	9/1/2017	Relapsed or refractory CD33+AML
Arsenic trioxide	Adults/Peds	NME*	9/5/2000	9/1/2017	APML
Clofarabine	Pediatrics	NME*	12/28/2004	9/1/2017	Refractory ALL
Nelarabine	Adults/Peds	NME*	10/28/2005	9/1/2017	T-cell ALL
Dasatinib	Adults/Peds	Targeted Therapy	6/28/2006	11/9/2017 12/21/2018	Ph+CML in the chronic phase PH+ ALL
Imatinib	Adults/Peds	Targeted	9/27/2006	11/9/2017	PH+ ALL and PH+ CML
Nilotinib	Adults/Peds	Targeted	10/29/2007	3/22/2018	Ph+CML in the chronic phase
Ipilimumab	Adults/Peds	MAB**	3/25/2010	7/21/2017	Unresectable or metastatic melanoma 12 yrs & up
Denosumab	Adults/Peds	MAB**	6/1/2010	6/13/2013	Giant cell tumor of the bone
Everolimus	Adults/Peds	Chemo	10/29/2010	9/25/2012	SEGA / subependymal giant cell astrocytoma.
Erwinia asparaginase	Adults/Peds	NME*	11/18/2011	11/18/2011	ALL
6-MP oral solution**	Adults/Peds	NME*	4/28/2014	4/28/2014 3/14/2017 5/23/2017	ALL (Liquid formulation approved) Mercaptopurine refractory classical cHL Micosatellite instability-high (MSI-H) or mismatch repair deficient solid tumor
Pembrolizumab	Adults/Peds	MAB**	9/4/2014	6/13/2018 12/19/2018	Adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma Metastatic Merkel cell carcinoma (≥12 years)
Dinutuximab	Pediatrics	NME*	3/10/2015	3/10/2015	High risk NBL
Avelumab	Adults/Peds	MAB**	3/23/2017	3/23/2017	Metastatic Merkel cell carcinoma (≥12 years)
Tisagenlecleucel	Pediatrics	NME*	8/30/2017	8/30/2017	Relapsed or refractory ALL
Emapalumab	Adults/Peds	NME*	11/20/2018	11/20/2018	Relapsed or refractory HLH
Larotrectinib	Adults/Peds	NME*	11/26/2018	11/26/2018	Solid tumor with (NTRK) gene fusion

Supportive Care Oncology Drugs to treat pediatric patients with toxicity associated with cancer treatment

Pegfilgrastim	Adults/Peds		1/31/2002	11/13/2015	Decrease incidence of infection, increases survival in patients acutely exposed to myelosuppressive doses of radiation
Rasburicase	Adults/Peds	NME*	7/12/2002	7/12/2002	Management of plasma uric acid levels in patients at risk for tumor lysis syndrome
Palifermin	Adults/Peds		12/15/2004		Decreased incidence and duration of severe oral mucositis
Levofolacin	Adults/Peds		3/7/2008	3/7/2008	Rescue after HD-MTX
Tocilizumab	Adults/Peds		1/8/2010	8/30/2017	Treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome
Voraxaze	Adults/Peds		1/17/2012	1/17/2012	Treatment of toxic plasma methotrexate concentration based on delayed MTX clearance

*NME = New Molecular Entities

** MAB= Monoclonal Antibody

*** Approval was based primarily on pediatric clinical trial results, exact pediatric-specific approval date is unknown.