

## FDA Drug Approvals

Each month the FDA approves new medications, and below is a highlight of the most relevant new approvals and/or drugs which have the potential to impact your prescription plan. While the medications below have been evaluated and approved by the FDA, they may not enter the marketplace for several weeks or months. Therefore, pricing information for these medications is typically unavailable at the time of approval.

New Brand Approvals			
Drug Name	Uses/Treatment	Estimated Pricing Information	Other Information
Dupixent (dupilumab)	Treatment of moderate-to-severe atopic dermatitis	\$2,900 monthly	<ul style="list-style-type: none"> <li><b>Drug Information:</b> Dupixent is administered by subcutaneous injection once every two weeks. It works by blocking the inflammatory processes associated with atopic dermatitis.</li> <li><b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li><b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li><b>Clinical Concierge:</b> Dupixent is subject to MedTrak's 90 day new drug hold process and is currently undergoing clinical evaluation.</li> <li><b>BIC SpecialtyRx:</b> Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network.</li> </ul>
Kisqali (ribociclib)	Treatment of postmenopausal women with HR(+), HER2(-) advanced or metastatic breast cancer	\$11,170 monthly	<ul style="list-style-type: none"> <li><b>Drug Information:</b> Kisqali is indicated for use in combination with an aromatase inhibitor as initial endocrine-based therapy.</li> <li><b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li><b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li><b>BIC SpecialtyRx:</b> Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network.</li> </ul>
Ocrevus (ocrelizumab)	Treatment of patients with relapsing or primary progressive forms of multiple sclerosis (MS)	\$65,000 annually	<ul style="list-style-type: none"> <li><b>Drug Information:</b> Ocrevus is the first drug approved for treating primary progressive MS. It is administered by IV infusion once every six months.</li> <li><b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li><b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li><b>Clinical Concierge:</b> Ocrevus is subject to MedTrak's 90 day new drug hold process and is currently undergoing clinical evaluation.</li> <li><b>BIC SpecialtyRx:</b> Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network.</li> </ul>

## Drug Recalls

Drug recalls are actions taken by drug manufacturers to remove a product from the market. Recalls may be conducted by the manufacturer on their own initiative, by request of the FDA, or mandated by the FDA. Below is a highlight of the most relevant drug recalls.

Drug Recalls			
Drug Name	Type of Recall	Reason for Recall	Recalling Firm
Nano PNC Water	Voluntary	Marketed without an Approved NDA/ANDA and non-sterility: NANO PNC Water by nebulizer was sampled and found to contain variovorax paradoxus.	Pacific Medical Solutions 13967 Campo Rd Ste 102 Jamul, CA 91935-3232

*The Clinical Care Center (CCC) is MedTrak's comprehensive clinical solution to control costs and increase adherence for our Clients and Members. The Clinical Care Center is made up of 7 Steps to Improved Outcomes: Generics Plus, Formulary Management, Member & Client Education, RightChoice, Control Trak, Best-In-Class (BIC) SpecialtyRx, and Clinical Concierge.*

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Drug Name	Uses/Treatment	Estimated Pricing Information	Other Information
Austedo (deutetrabenazine)	Treatment of chorea associated with Huntington's disease	\$5,000 monthly	<ul style="list-style-type: none"> <li><b>Drug Information:</b> Austedo is an oral medication for the treatment of chorea, abnormal involuntary movement, associated with Huntington's disease.</li> <li><b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li><b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li><b>Clinical Concierge:</b> Austedo is subject to MedTrak's 90 day new drug hold process and is currently undergoing clinical evaluation.</li> <li><b>BIC SpecialtyRx:</b> Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network.</li> </ul>
Ingrezza (valbenazine)	Treatment of adults with tardive dyskinesia	\$6,000 monthly	<ul style="list-style-type: none"> <li><b>Drug Information:</b> Ingrezza is an oral medication used for the treatment of tardive dyskinesia, involuntary movements of the tongue, lips, face, trunk, and extremities that typically due to long-term use of neuroleptic drugs that treat psychiatric conditions.</li> <li><b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li><b>Control Trak:</b> Subject to Max Dollar and Max Dose</li> </ul>

			<p>edits.</p> <ul style="list-style-type: none"> <li>• <b>Clinical Concierge:</b> Ingrezza is subject to MedTrak's 90 day new drug hold process and is currently undergoing clinical evaluation.</li> </ul>
<p>RoxyBond (oxycodone)</p>	<p>Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate</p>	<p>Pricing information not yet available</p>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> RoxyBond is an abuse-deterrent formulation of oxycodone that uses physical and chemical barriers to deter abuse, without the use of aversive agents or opioid antagonists.</li> <li>• <b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li>• <b>Control Trak:</b> Subject to the Opioid Chronic Use, Max Dollar, and Max Dose edits.</li> </ul>
<p>Brineura (cerliponase)</p>	<p>Indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2</p>	<p>Pricing information not yet available</p>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> Brineura is administered into the cerebrospinal fluid by infusion via a surgically implanted reservoir and catheter</li> <li>• <b>Formulary Management:</b> Considered non-preferred upon market entry and will likely be limited to the medical benefit only.</li> </ul>
<p>Rydapt (midostaurin)</p>	<p>Treatment of acute myeloid leukemia (AML), aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)</p>	<p>Pricing information not yet available</p>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> Rydapt is an oral kinase inhibitor for the treatment of various types of leukemia.</li> <li>• <b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li>• <b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li>• <b>Clinical Concierge:</b> Rydapt will be subject to prior authorization upon market entry.</li> <li>• <b>BIC SpecialtyRx:</b> Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network.</li> </ul>
<p>Tymlos (abaloparatide)</p>	<p>Treatment of postmenopausal women with osteoporosis at high risk for fracture</p>	<p>Pricing information not yet available</p>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> Tymlos is a subcutaneous parathyroid hormone peptide analog indicated for the treatment of osteoporosis in postmenopausal women who are at high risk for fracture.</li> <li>• <b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li>• <b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li>• <b>Clinical Concierge:</b> Tymlos will be subject to MedTrak's 90 day new drug hold process and will undergo clinical evaluation upon market entry.</li> <li>• <b>BIC SpecialtyRx:</b> Comprehensive clinical management and competitive discounts via MedTrak's BIC Specialty Pharmacy Network.</li> </ul>
<p>Alunbrig (brigatinib)</p>	<p>Second-line treatment of ALK-positive metastatic non-small cell lung cancer (NSCLC)</p>	<p>Pricing information not yet available</p>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> Alunbrig is an oral kinase inhibitor for the treatment of ALK-positive metastatic NSCLC for patients who have progressed on or are intolerant to Xalkori.</li> <li>• <b>Formulary Management:</b> Considered non-preferred upon market entry.</li> <li>• <b>Control Trak:</b> Subject to Max Dollar and Max Dose edits.</li> <li>• <b>Clinical Concierge:</b> Alunbrig will be subject to prior authorization upon market entry.</li> </ul>

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Vancomycin Injection	Voluntary	Presence of particulate matter	Hospira Inc., A Pfizer Company 275 N Field Dr Lake Forest, IL 60045-2579 Pacific
Ibuprofen Injection	Voluntary	Presence of particulate matter	X-Gen Pharmaceuticals Inc. 300 Daniel Zenker Dr Horseheads, NY 14845-1014

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