

## 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.

New Approvals		
Drug Name	Uses/Treatment	Plan Impact & CCC Management Strategy
<b>Repatha</b>	Treatment of <b>certain types of high cholesterol</b>	<ul style="list-style-type: none"> <li>• <b>Highly anticipated second in class:</b> Repatha is the second agent to be approved in the new “PCSK9” drug category. It is approved only for those who have already maximized statin therapy and have either heterozygous familial hypercholesterolemia (HeFH), clinical atherosclerotic cardiovascular disease, or homozygous familial hypercholesterolemia (HoFH). It is administered by injection every two weeks.</li> <li>• <b>Formulary Management:</b> considered non-preferred upon market entry.</li> <li>• <b>Cost (AWP):</b> cost has not been released, but should remain competitive with Praluent</li> <li>• <b>BIC SpecialtyRx:</b> subject to comprehensive clinical management through MedTrak’s BIC Specialty program and obtained with a competitive discount.</li> <li>• <b>Clinical Concierge:</b> subject to prior authorization as a specialty medication. Drug-specific and evidence-based criteria developed and applied by MedTrak’s Clinical Care Center to ensure appropriate utilization. Praluent and Repatha are being evaluated for preferred product opportunity within this drug category.</li> </ul>
<b>Addyi</b>	Treatment of <b>hypoactive sexual desire disorder (HSDD)</b>	<ul style="list-style-type: none"> <li>• <b>First in class for women:</b> Addyi is the first agent in a new drug class used in the treatment of low sexual drive in premenopausal females. It is not indicated to enhance sexual performance or to be used in postmenopausal women. Unlike Viagra, which is taken on an as needed basis, Addyi is to be taken daily.</li> <li>• <b>Formulary Management:</b> Not yet available, but will be considered non-preferred upon market entry.</li> <li>• <b>Cost (AWP):</b> undetermined</li> <li>• <b>Clinical Concierge:</b> subject to prior authorization under MedTrak’s Enhanced Management program. Drug-specific and evidence-based criteria developed and applied by MedTrak’s Clinical Care Center to ensure appropriate utilization.</li> </ul>
<b>Synjardy</b>	Treatment of <b>type 2 diabetes</b>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> Synjardy is a combination product containing the Jardiance (empagliflozin) and metformin and is indicated for the treatment of type 2 diabetes.</li> </ul>

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		<ul style="list-style-type: none"> <li>• <b>Formulary Management:</b> Not yet commercially available, but will be considered non-preferred upon market entry.</li> <li>• <b>Cost (AWP):</b> Cost has not been released</li> </ul>
<p><b>Erlotinib (generic for Tarceva)</b></p>	<p>Treatment of <b>Non-Small Cell Lung Cancer (NSCLC) &amp; Pancreatic Cancer</b></p>	<ul style="list-style-type: none"> <li>• <b>Drug Information:</b> Erlotinib is first tyrosine kinase inhibitor (EGFR-TKI) to be approved generically.</li> <li>• <b>Formulary Management:</b> considered non-preferred upon market entry.</li> <li>• <b>Cost (AWP):</b> cost has not been released</li> <li>• <b>BIC SpecialtyRx:</b> subject to comprehensive clinical management through MedTrak’s BIC Specialty program and obtained with a competitive discount. Since Tarceva is on MedTrak’s Oncology Split-Fill Program, erlotinib will also be a part of this program.</li> <li>• <b>Clinical Concierge:</b> subject to prior authorization as a specialty medication. Drug-specific and evidence-based criteria developed and applied by MedTrak’s Clinical Care Center to ensure appropriate utilization.</li> </ul>

*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.*