

Review of new products
WY-DUR
February 14, 2019

A Medline search was conducted January 28, 2018.

Epidiolex (Cannabidiol): Approved for treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients ≥ 2 years of age.

Mechanism of action: Unknown.

Other medications in the market basket: Clobazam, felbamate, lamotrigine, rufinamide, topiramate,

Decision type: 2 – other drugs approved for indication. Seizure diagnosis required for all agents in class.

No comparative evidence.

Dupixent (dupilumab): Approved as add-on maintenance treatment for moderate to severe asthma in patients 12 years and older with eosinophilic phenotype or with corticosteroid dependent asthma. (Previously reviewed for atopic dermatitis indication.)

Mechanism of action: Mechanism in asthma has not been definitively established.

Other medications in the market basket: Nucala, Xolair, Cinqair

Decision type: 2 – other drugs approved for indication. Other medications in the market basket are not allowed through point of sale system. They are physician administered. Dupixent may be self-administered with proper training.

No comparative evidence.

Medical Letter review conclusion: Add-on maintenance treatment with dupilumab (Dupixent) can improve lung function and reduce severe exacerbations and oral corticosteroid use in patients >12 years old with moderate to severe asthma, particularly those with an eosinophilic phenotype. How dupilumab compares to the other monoclonal antibodies that are approved for treatment of eosinophilic asthma remains to be determined, and its long-term safety is unknown.

Yupelri (revefenacin inhalation): Approved for maintenance treatment of chronic obstructive pulmonary disease (COPD)

Mechanism of action: Long-acting muscarinic antagonist competitively and reversibly inhibiting the action of acetylcholine at type 3 muscarinic receptors in bronchial smooth muscle causing bronchodilation.

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Other medications in the market basket: Tudorza, Seebri, Spiriva, Atrovent, Incruse

Decision type: 3 – New drug, current PDL Class.

No comparative evidence

Cequa (cyclosporine ophthalmic): Approved for keratoconjunctivitis sicca

Mechanism of action: Exact mechanism is unknown. Increases tear production when suppressed tear production is presumed to be associated with keratoconjunctivitis sicca-associated ocular inflammation (in patients not using topical anti-inflammatory drugs or punctal plugs).

Other medications in the market basket: Cyclosporine in Klarity, Restasis, Xiidra

Decision type: 3 – New drug, current PDL Class.

No comparative evidence.

Emgality (galcanezumab-gnlm injection): Approved for prevention of migraine in adults.

Mechanism of action: Monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand blocks its binding to the receptor.

Other medications in the market basket: Aimovig and Ajovy. Many other drugs for migraine prophylaxis, including beta blockers, tricyclic antidepressants, topiramate and divalproex sodium/valproic acid.

Decision type: 2 – Other drugs approved for indication. Clinical criteria applies.

No direct comparative evidence

Author, Year	Study Design	Results
Mitsikostas, 2017	Comparisons across randomized controlled studies, including eptinezumab, erenumab, galcanezumab, and fremanezumab.	All four CGRP antibodies display comparable efficacy that does not differ significantly from currently available oral antimigraine drugs. Safety and tolerability profiles and low frequency of administration looks promising but remains to be verified in long-term and large-scale trials.

Medical Letter review conclusion: In short-term clinical trials, the subcutaneously injected CGRP antagonists fremanezumab-vfrm (Ajovy) and galcanezumab-gnlm (Emgality) were more effective than placebo in preventing migraines in adults with episodic or chronic migraine and were generally well

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tolerated. These drugs have not been compared to other migraine preventive treatments, most of which are available generically in oral formulations, and their long-term efficacy and safety are unknown. They may be effective when other therapies have failed.

References:

1. Drug Facts and Comparisons[®]. Facts & Comparisons 4.0 Online. Indy (IN): Wolters Kluwer Health Inc.; 2008. Available from: <http://www.online.factsandcomparisons.com>. Accessed: January 31, 2019.
2. Dupilumab (Dupixent) for Asthma. *The Medical Letter on Drugs and Therapeutics*. 2019; 61(1563): 6 – 8.
3. Mitsikostas D and Reuter U. Calcitonin gene-related peptide monoclonal antibodies for migraine prevention: comparisons across randomized controlled trials. *Curr Opin Neurol*. 2017; 30: 272 – 280.
4. Fremanezumab (Ajovy) and Galcanezumab (Emgality) for Migraine Prevention. *The Medical Letter on Drugs and Therapeutics*. 2018; 60(1559): 177 – 180.