

New Indication Approvals for Existing

1. Linzess (linaclotide)

- **Old drug:** Linaclotide — guanylate cyclase-C agonist used for adult IBS-C & chronic constipation.
- **New indication:** *Approved for children 7 years and older with irritable bowel syndrome with constipation.*
- **Approved: November 4, 2025**
- **Context:** Label extension expanding use to pediatric patients.

2. Caplyta (lumateperone)

- **Old drug:** Atypical antipsychotic originally for schizophrenia and bipolar depression.
- **New indication:** *Approved as adjunctive therapy for major depressive disorder (MDD) in adults.*
- **Approved: November 5, 2025**

3. Imfinzi (durvalumab)

- **Old drug:** PD-L1 immune checkpoint inhibitor (multiple cancer uses).
- **New indication:** *Approved as perioperative immunotherapy for early gastric and gastroesophageal cancers.*
- **Approved: November 25, 2025**

4. Darzalex Faspro (daratumumab + hyaluronidase)

- **Old drug:** CD38-targeted myeloma therapy.
- **New indication:** *Approved for newly diagnosed light chain (AL) amyloidosis.*
- **Approved: November 19, 2025**
- **Also approved earlier in November for high-risk smoldering multiple myeloma.*

5. Eylea HD (aflibercept)

- **Old drug:** VEGF inhibitor for retinal diseases.
- **New indication:** *Approved for treatment of macular edema following retinal vein*

occlusion (RVO) and monthly dosing across indications.

- **Approved: November 19, 2025**

6. Uplizna (inebilizumab-cdon)

- **Old drug:** CD19-directed antibody.
- **New indication:** *Approved for generalized myasthenia gravis in adults.*
- **Approved: December 11, 2025**

7. Accrufer (ferric maltol)

- **Old drug:** Oral iron therapy for iron deficiency in adults.
- **New indication:** *Approved for children 10 years and older.*
- **Approved: December 19, 2025**

8. Addyi (flibanserin)

- **Old drug:** Serotonin receptor modulator for hypoactive sexual desire disorder.
- **New indication:** *Approved for use in postmenopausal women.*
- **Approved: December 13, 2025**

9. Orladeyo (berotralstat)

- **Old drug:** Plasma kallikrein inhibitor for hereditary angioedema (HAE).
- **New indication:** *Approved oral pellets for pediatric patients (2 to <12 years).*
- **Approved: December 11, 2025**

10. Wegovy (semaglutide)

- **Old drug:** GLP-1 receptor agonist for obesity/weight management.
- **New indication:** *Approved oral pill formulation for weight loss in adults.*
- **Approved: December 22, 2025**

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