

# Emerging Therapies

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# Definitions

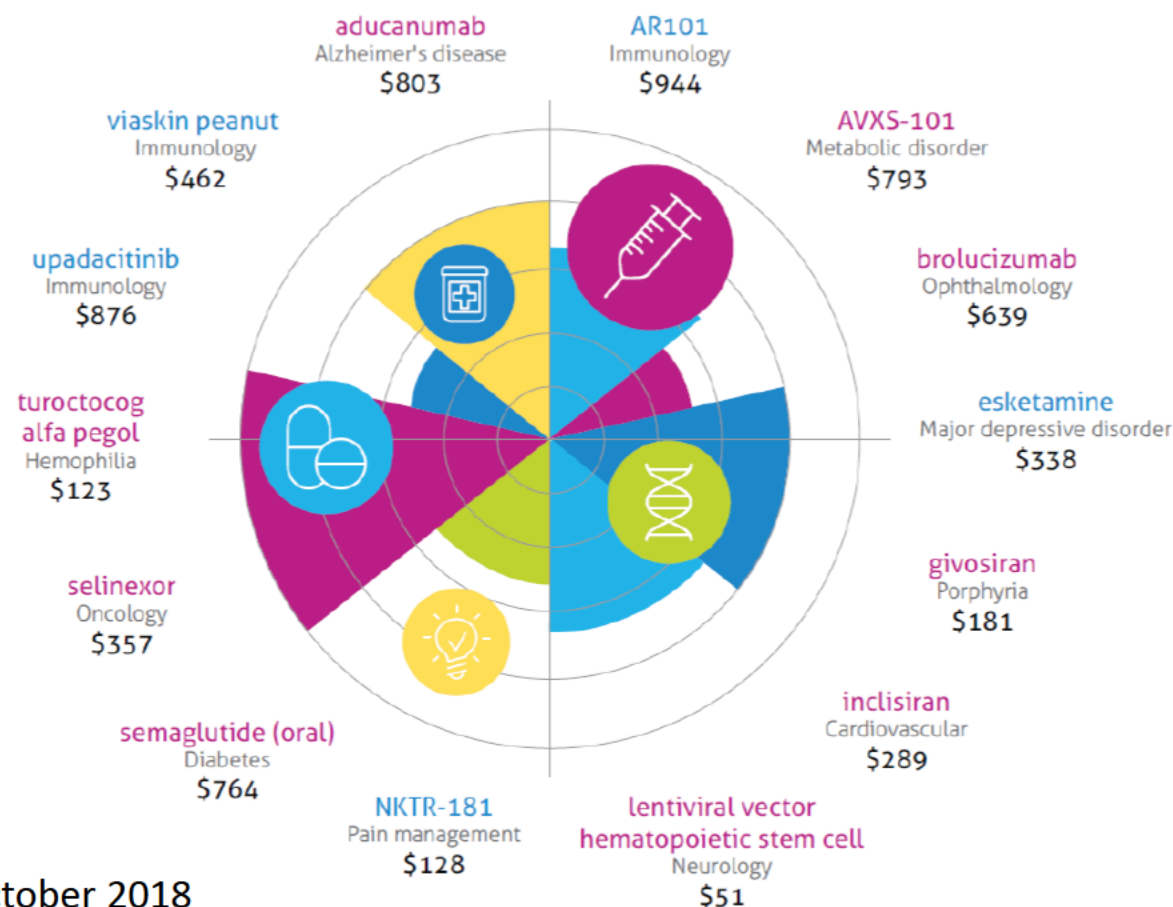
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- ▶ “Emerging therapy” means a new drug with a novel mechanism of action including gene therapy
- ▶ “High-Cost Drug” means a covered outpatient drug that has an estimated cost  $\geq$  \$100,000 per patient per year
- ▶ “Orphan Drug” means a drug that treats a condition that affects less than 200,000 individuals in the U.S.

# Emerging therapies continue to grow and influence the clinical and financial landscape

## Of those drugs in Phase III trials...

- ✓ 60% are specialty drugs
- ✓ 33% are orphan drugs
- ✓ 13% are considered breakthrough therapies
- ✓ Only 8% are biosimilars



## Of the applications submitted to the FDA...

- ✓ 25% of new drug applications submitted to the FDA have been granted "priority review"

Source: Magellan, MRx Pipeline October 2018

# How HCA determines coverage status of new drugs—including emerging therapies

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## ▶ Medicaid must cover drugs:

- ▶ For their FDA-approved or medically-accepted indications;
- ▶ That are included in the Medicaid Drug Rebate Program; and
- ▶ That are medically necessary.

## ▶ Employee & Retiree benefits plans must cover drugs that are:

- ▶ FDA approved.
- ▶ Medically necessary.

## ▶ New drugs and emerging therapies must be reviewed by the PEB Board (budget proviso).

# How HCA develops clinical policies for emerging therapies

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- ▶ Identify new drugs or new indications approved by FDA
- ▶ Perform a critical evaluation of the available evidence
  - ▶ Drug Effectiveness Review Project (DERP)
  - ▶ Medicaid Evidenced-Based Decision Making (MED)
  - ▶ Clinical staff
- ▶ Determine the strength of the evidence
- ▶ Develop standard clinical policies for therapies based on:
  - ▶ Strength of evidence.
  - ▶ Efficacy, effectiveness, and safety.
  - ▶ Impacts on health outcomes.
  - ▶ Indications for use.
  - ▶ Alternative therapies.
- ▶ For therapies with poor quality evidence, determine medical necessity on a case-by-case basis.

# How HCA develops clinical policies

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## ▶ Medicaid

- ▶ HCA Clinical staff develop draft policies
- ▶ Draft policies reviewed, edited, and approved by the Drug Utilization Review Board in open public meetings
- ▶ Working toward standardized policies across Medicaid programs

## ▶ Employee & Retiree Benefits Plans

- ▶ Uniform Medical Plan – clinical policies reviewed, edited, and approved by the Pharmacy & Therapeutics committee of the benefit administrators
  - ▶ Regence develops policies for drugs covered under the medical benefit
  - ▶ Moda develops policies for drugs covered under the pharmacy benefit
- ▶ Fully-insured plans develop own clinical policies

# Medicaid is creating a high-cost drug policy

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## ▶ High-cost drug definition

- ▶ Covered outpatient drug
- ▶ Traditional drug, orphan drug, gene therapy
- ▶ Expected annual cost is  $\geq$  \$100,000

## ▶ HCA will work with representatives from Medicaid managed care plans to:

- ▶ Identify high-cost drugs
- ▶ Develop clinical policies
- ▶ Carve new high-cost drugs out of MCO rates when it:
  - Is indicated by a disease previously untreated with drugs.
  - Has a new mechanism of action than existing high-cost drugs, costs 50% more than existing high-cost drugs, and was given breakthrough designation by the Food and Drug Administration.
  - Has the same mechanism of action as current high-cost drugs that are already carved out of the MCO rate.





# Questions?

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