Emerging Therapies
House Health Care and Wellness Committee
January 18, 2019

Judy Zerzan, MD, MPH
Chief Medical Officer
Clinical Quality and Care Transformation
Definitions

“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 ≥ $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

- 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

- 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

- 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

**High-cost drug definition**
- Covered outpatient drug
- Traditional drug, orphan drug, gene therapy
- Expected annual cost is ≥ $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?

Judy Zerzan
Chief Medical Officer
360-725-1612
judy.zerzan@hca.wa.gov