FAST TRACK DRUGS & EMERGING TECHNOLOGIES WORKGROUP

August 25, 2020

Fast Track & Emerging Technologies Agenda

Welcome & Introductions
Call to Order
Call for Public Comment
Agenda Items

- Review charge of workgroup as described in the 2020 Virginia Acts of Assembly Chapter 1289, Item 313.CCCCC
- Opening Remarks and Summary of MCO Responses to pre-meeting Questions
- FDA Fast-track Drugs and Emerging-break-through-technologies
- Identifying drugs/technologies for prior/service authorization criteria
- Identifying & establishing thresholds for drugs & technologies that require prior authorization
- DMAS Published Criteria and Contract Implications
- Other Considerations
- Questions & Closing Remarks

2020 Virginia Acts of Assembly Chapter 1289, Item 313.CCCCC

- Establish a "workgroup of Medicaid managed care organizations, physicians and pharmacists and other stakeholders, as necessary, to assess policies and procedures, including risk sharing arrangements, reimbursement methods or other **mechanisms to determine Medicaid coverage** and reimbursement of **FDA fast-track drugs and emerging-break-through technologies.** The assessment shall include an examination of other states' approaches to determine Medicaid coverage, **clinical criteria for coverage across the fee-for-service and managed care programs**, risk sharing arrangements, and reimbursement methodologies including kick-payments or other pass-through arrangements that are consistent with the utilization and cost of the drug or technology. The assessment will also examine and make recommendations regarding the timeline for providing coverage from the date of FDA approval of the drug or technology."

Fast Track Drugs & Emerging Technologies Workgroup

- Today's Clinical Meeting
  - Facilitated by DMAS OCMO
  - Identifying "fast track drugs & emerging technologies"
  - Development of clinical criteria
  - Implications for MCOs

- Financial Meeting
  - Facilitated by DMAS Provider Reimbursement
  - Review of reimbursement strategies

Workgroup Participants

- MCO Leadership
  - CEOs, CMOs, CFOs and Pharmacy Directors
- DMAS Leadership
  - CMO, CFO, Pharmacy Manager, Provider Reimbursement, CCC Plus & Medallion 4.0, Appeals, Policy
- Virginia Department of Budget and Planning
- Virginia General Assembly Money Committees
- Virginia Association of Health Plans

FDA Definitions

- Fast Track
  - A process designed to expedite the development and review of drugs to treat serious conditions and fill an unmet medical need.
  - 2019 – 29 drugs approved
  - 2020 – 20 drugs approved as of 6/30/2020
- Emerging Technologies (Breakthrough Therapy)
  - A process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).
  - 2019 – 26 approvals
  - 2020 – 17 approvals as of 6/30/2020

Medicaid Drug Benefit

- Defined by Social Security Act 1927 (the Act)
  - Medicaid programs are required to cover all drugs that are
    - FDA approved
    - Medically necessary
    - Manufactured by a pharmaceutical company participating in the Medicaid Drug Rebate Program
  - The Act allows the Medicaid program to develop preferred drug lists (PDLs) and exclude drugs from the PDL as long as a service authorization (SA) process is established
- CCC Plus and Medallion 4.0 contracts
  - Require MCOs to comply with drug coverage as described in the Act

DMAS Drug Review Process for Drugs Covered Under the Pharmacy Benefit

- Preferred Drug List/Common Core Formulary (PDL/CCF) Drugs
  - DMAS Pharmacy & Therapeutics Committee reviews all drugs subject to PDL/CCF and recommends utilization management controls including service authorization (SA) when deemed appropriate
  - P&T Committee does NOT review drugs covered **only** under the Medicaid medical benefit
  - Biannual meetings
  - New drugs to market are "non-preferred" until reviewed by Committee
  - DMAS contracts with a pharmacy benefit administrator to assist with criteria development and review all PDL/CCF service authorizations.

DMAS Drug Review Process Pharmacy Benefit Covered Drugs

- Drug Utilization Review (DUR) Board
  - DMAS DUR Board reviews all self-administered outpatient drugs NOT included on the PDL/CCF and recommends utilization management controls including service
  - DUR Board does NOT review drugs covered only under the Medicaid medical benefit
  - Quarterly meetings
  - Open access to new drugs not subject to PDL/CCF until reviewed by DUR Board
  - DMAS contracts with a pharmacy benefit administrator to assist with criteria development and review all DUR service authorizations.

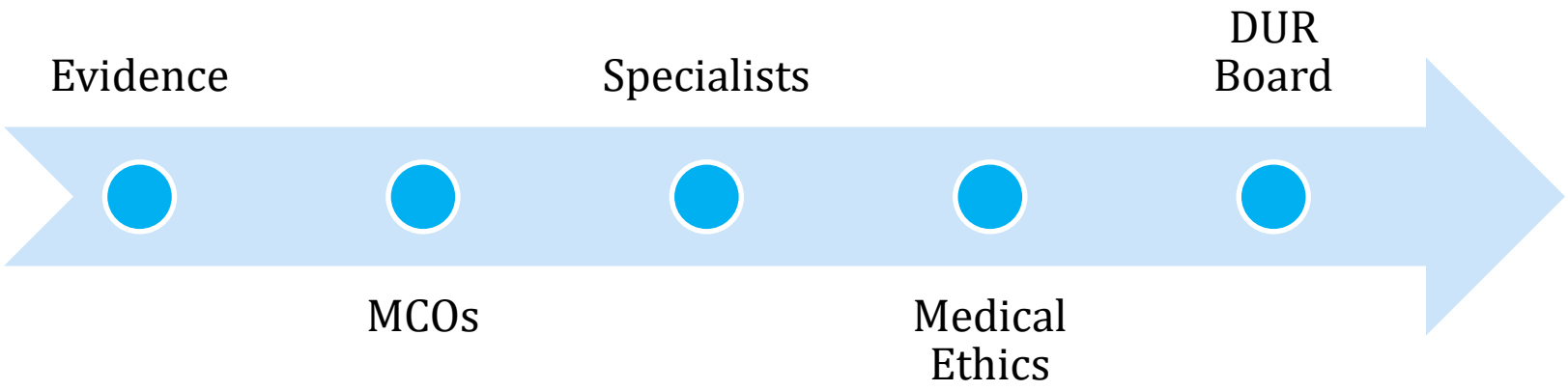
Other Medicaid Programs Clinical Criteria Process for Pharmacy Benefit Covered Drugs

- **Nevada:**
  - New PDL drugs are non-preferred until reviewed by the P&T Committee.
  - New non-PDL drugs are added to the Clinical PA List "C" and are forwarded to the state to handle until the drugs are reviewed by the DUR Board.
  - Once approved by the DUR Board, the pharmacy benefit administrator is responsible for reviewing PA requests.
  - Nevada has a limited number of drugs that remain on the Clinical PA List "C" and are reviewed by the state.

- **Michigan:**
  - Suspends all new drugs for approximately 6 months pending review by P&T.
  - Drug claims deny for "Drug Not Covered" with a supplemental message "Drug Exclusion – suspended medication".
  - During this time, prescribers may request a non-formulary PA for the new medication. All requests are reviewed by the state on a case-by-case basis.

DMAS Drug Review Process for Drugs Covered Under the Medical Benefit

- DMAS clinical staff determine which drugs require service authorization criteria as new J HCPCS codes are published
  - Service authorization criteria developed for select drugs by DMAS clinical staff
  - Criteria are not vetted by DMAS P&T Committee or DUR Board
  - For a subset of therapies, the DMAS staff engage in a more thorough review process



Review Process for Zolgensma

The Texas Medicaid Process

- Texas Medicaid
  - Clinician Administered Drug (CAD) Group
    - Newly released HCPCS codes for CADs and biologicals are reviewed by Texas Medicaid. If the CADs are determined to be appropriate benefits for Medicaid, then the HCPCS codes are presented at a rate hearing as part of the process to become a benefit. Review of any new CAD does not guarantee that the new CAD will become a benefit
    - CAD Handbook includes criteria for 50+ CADs
  - 3 full-time clinical pharmacists develop criteria for CADs

Pre-meeting Questions MCO Responses

How does your organization develop criteria for fast track & emerging technologies?

MCO 1

- *P&T meets quarterly. There is a separate committee that develops clinical policy bulletins for drugs and other treatments limited to the medical benefit, which also meets at least quarterly.*

MCO 2

- *P&T Committee reviews & approves clinical criteria/policy for Medicare, Medicaid, and Commercial plans. The Committee reviews available clinical evidence & supporting data to determine the clinical appropriateness of all our clinical criteria, including agents for the treatment of asthma. Criteria are generally base on high quality evidence, FDA approved indication(s), clinical practice guidelines, and input from clinical specialists. The primary goal of clinical criteria is to help ensure clinically appropriate use of drugs & therapies.*

MCO 3

- *Our PBM's National Pharmacy & Therapeutics Committee*

MCO 4

- *We develop guidelines for FDA and non-FDA fast-track/breakthrough drugs and technologies via an ongoing process that include a rigorous review based upon the most current evidence-based peer-reviewed medical literature, the input of appropriate medical specialists and key opinion leaders.*

MCO 5

- *At onset and per policy, medications designated to be reviewed are posted on the website on the 'Review at Launch Medication List'. Listed medications remain under this policy effective until such time that the Clinical P&T Committee reviews to determine pre-service reviews are no longer needed or the drugs are added to the Prior Authorization List.*

MCO 6

- *Criteria is developed based off of clinical practice guidelines, peer-reviewed literature, compendia, and physician specialists in a particular field. If available, Hayes technology reviews and CMS guidelines are also utilized.*

How long does it take? Who is involved?

MCO 1

- *Generally, there would be an approximate 90 day timeframe for review and policy development.*
- *Medical director(s), specialists or other experts, provider associations when necessary, and pharmacist(s).*

MCO 2

- *About 3 months. A few days after FDA approval for high profile specialty drugs*
- *Internal clinical staff, clinical specialists, and our P&T Committee.*

MCO 3

- *3-6 months*
- *National P&T*

MCO 4

- *On average these drug are reviewed within 90 days of launch to market.*
- *Clinical pharmacists, medical director leadership committee (MDLC), P&T Committee, and SMEs*

MCO 5

- *The process is generally in the range of 6 months*
- *P&T Committee members, Pharmacy Research team members, Corporate and market leaders.*

MCO 6

- *Review & implementation of criteria depends on the complexity of the therapy. Though the P&T and HQUM (Healthcare Quality & Utilization Management) Committee meetings occur quarterly and oversee pharmacy and medical policies, there is a process which accommodates expedited criteria approval. Usually, these occur within less than 30 days if a critical need is established.*
- *Pharmacists, Medical Directors, and Subject Matter experts within the Commonwealth.*

How should we define the right subset of drugs and technologies to focus on?

MCO 1

- *The list of drugs/technologies for focused review should be based on defined criteria developed in collaboration with DMAS/MCOs.*

MCO 2

- *Assuming Mercer is the source, we recommend list be shared with MCOs P&T committee.*

MCO 3

- *Focus should be driven by need/ demand for new products. However, attention must also be paid to any new drugs/ technologies that are very high cost that have not been captured in this subset.*

MCO 4

- *Focus on therapies that impact total cost of care. Priority should be given to therapies that have a higher impact on the total cost of care and create a greater expenditure for the MCOs, DMAS and the state of Virginia.*

MCO 5

- *We offer that there may be significant value for DMAS and MCOs to focus on the drugs and technologies highlighted in the GA budget language.*

MCO 6

- *DMAS needs to assess MCO Risk with respect to high cost emerging therapies.*

How should DMAS develop criteria for these therapies?

MCO 1

- *Consideration for a workgroup with appropriate specialists, MCOs, and DMAS would be needed. Reviews should occur irrespective of whether a pharmacy or medical benefit. It is important on many of these new drugs/technologies to have consistent criteria across MCO's*

MCO 2

- *We ask that DMAS to keep in mind, FDA regulatory approval is necessary, but not sufficient for coverage. This can be problematic when "approval" is based on limited data, without evidence of a net health benefit (for example, 510(k) clearance).*

MCO 3

- The development of new policies should be need, cost, and anticipated utilization driven. It is also important to understand any potential negative impact to members and/or regulators and/or providers depending on the strictness of the criteria.

MCO 4

- *We encourage developing a medical exception policy outlining the terms for approval. Policies should be created collaboratively between DMAS and MCOs with each policy being consistent among each MCO that participate within the Virginia Medicaid program.*

MCO 5

- *We recommend that DMAS develop a collaborative framework among DMAS & MCOs for the current and emerging pipeline of novel and or high-cost drugs and treatments. Each new drug approval would be reviewed against a pre-defined set of criteria related to cost, indicated conditions, evidence of efficacy in improving outcomes for indicated conditions, safety of use and FDA approval type.*

MCO 6

- *Criteria should be created collaboratively with DMAS, the MCO's, and experts in the field.*

Key Discussion Questions

- How should we define the right subset of drugs and technologies to focus on?
- How should we develop criteria for these drugs?
- What are the contract implications of DMAS published criteria?

Next steps

- Early September – Financial discussion
- Draft report
  - Complete no later than September 14
  - Share with MCOs for comment
    - Responses to DMAS by September 16
- Final report to HHR
  - September 29, 2020