COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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January 4, 2021

MEMORANDUM

TO: The Honorable Janet D. Howell
Chair, Senate Finance Committee

The Honorable Luke E. Torian
Chair, House Appropriations Committee

The Honorable Mark D. Sickles
Vice Chair, House Appropriations Committee

FROM: Karen Kimsey
Director, Virginia Department of Medical Assistance Services

SUBJECT: FDA Fast-Track Drugs and Emerging-Break-Through Technologies Workgroup

This report is submitted in compliance with the Virginia Acts of the Assembly – HB30 (Chapter 1289), Item 313, CCCCC, which states:

"The Department of Medical Assistance Services shall 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. The workgroup shall report on issues and recommendations to the Joint Subcommittee for Health and Human Resources Oversight by September 1, 2020, including any budgetary or regulatory authority required to implement changes for such coverage."

Should you have any questions or need additional information, please feel free to contact me at (804) 786-8099.
KK
Enclosure
Pc: The Honorable Daniel Carey, M.D., Secretary of Health and Human Resources

FDA Fast Track Drugs and Emerging Breakthrough Technologies Report

A Report to the Virginia General Assembly

December 1, 2020

Report Mandate:

The 2020 Appropriations Act Item 313.CCCCC. states, "The Department of Medical Assistance Services shall 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. The workgroup shall report on issues and recommendations to the Joint Subcommittee for Health and Human Resources Oversight by September 1, 2020, including any budgetary or regulatory authority required to implement changes for such coverage."

I. Executive Summary

In recent years, drug development technologies, platforms, and processes have evolved, contributing to an increase in novel drugs and technologies. In response, the FDA created a number of expedited approval pathways including the Breakthrough Therapy process and the Fast Track process. These pathways speed the market entry of promising therapies but often with limited evidence of efficacy, safety, or cost-effectiveness. Therapies approved through these expedited pathways are often more costly. As of 2019, 60% of all new drug approvals benefited from at least one of the expedited approval pathways.

The Department of Medical Assistance Services (DMAS) facilitated two workgroup meetings with stakeholders including physicians, pharmacists and leadership from both DMAS and the six Managed Care Organizations (MCOs) contracted with DMAS to address coverage and clinical criteria for therapies approved through the fast track and breakthrough therapy programs, as well as risk sharing arrangements and reimbursement methodologies. Under Section 1927 of the Social Security Act, Medicaid programs are required to cover all FDA-approved drugs that participate in the Medicaid Drug Rebate Program. Given federal requirements mandating Medicaid coverage, the workgroup focused not on whether the Agency covers certain therapies, but how to create

About DMAS and Medicaid

DMAS's mission is to improve the health and well-being of Virginians through access to high-quality health care coverage.

DMAS administers Virginia's Medicaid and CHIP programs for more than 1.6 million Virginians. Members have access to primary and specialty health services, inpatient care, behavioral health as well as addiction and recovery treatment services. In addition, Medicaid long-term services and supports enable thousands of Virginians to remain in their homes or to access residential and nursing home care.

Medicaid members historically have included children, pregnant women, parents and caretakers, older adults, and individuals with disabilities. In 2019, Virginia expanded the Medicaid eligibility rules to make health care coverage available to more than 400,000 newly eligible, low-income adults.

Medicaid and CHIP (known in Virginia as Family Access to Medical Insurance Security, or FAMIS) are jointly funded by Virginia and the federal government under Title XIX and Title XXI of the Social Security Act. Virginia generally receives a dollar-for-dollar federal spending match in the Medicaid program. Medicaid expansion qualifies the Commonwealth for a federal funding match of no less than 90 percent for newly eligible adults, generating cost savings that benefit the overall state budget.

appropriate clinical standards for FDA fast track drugs and emerging breakthrough technologies, and how to best manage their costs.

In the discussion on the process for clinical criteria development, most stakeholders agreed the focus should be on FDA fast track drugs and emerging breakthrough therapies, especially orphan drugs and gene therapies, which may treat conditions with few or no available alternative treatments, low prevalence, and very high cost. Stakeholders emphasized the need for a collaborative process between DMAS and the managed care organizations (MCOs) to develop standardized criteria for these therapies. As part of the discussion, DMAS noted that moderate to substantial resources would be required to accomplish this goal.

In the discussion on risk sharing and reimbursement methodologies, DMAS presented five risk mitigation models: risk pool (DMAS' current approach), partial carve-out, risk corridor, kick payments, and individual reinsurance (or stop-loss). DMAS led a discussion detailing the implications and trade-offs for each model with respect to the level of risk assumed by both DMAS and the contracted MCOs. Finally, DMAS reviewed approaches used by other states, noting that several states have recently adopted a carve-out approach.

By the end of the workgroup sessions, the six MCOs were unanimous in their recommendation that DMAS return to an individual reinsurance methodology, which had been implemented between 2013 and 2018.

II. Workgroups

DMAS facilitated two workgroup meetings on August 25, 2020 and September 1, 2020. The first workgroup meeting addressed coverage and clinical criteria across the fee-for-service and managed care programs. Relevant background information and the information from this clinical criteria workgroup are collected into Sections III and IV of this report. The second workgroup meeting addressed risk sharing arrangements and reimbursement methodologies. The information from this financial consideration workgroup meeting was collected into Section V of this report. To inform workgroup discussions, prior to the meetings, DMAS requested the MCOs review and respond to questions related to criteria development and reimbursement for FDA fast track drugs and emerging breakthrough technologies (See Appendix D)

Stakeholders invited to each meeting included physicians, pharmacists, leadership from DMAS, the Agency's contracted MCOs, the Department of Planning and Budget, staff from the Virginia General Assembly Money Committees, and the Virginia Association of Health Plans. Attendance is included in Appendix A.

III. Background

Since the FDA first developed an expedited drug review process in 1988 in response to the AIDS epidemic, the FDA's approval and regulatory processes have continued to evolve and increase in complexity. Currently, the FDA has developed four processes to expedite the availability of new drugs; the most recent of these is the Breakthrough Therapy process, which began in 2012. The goal of these programs is to bring new drugs and therapies to patients faster, especially when the drugs will fill an unmet medical need or bring substantial improvement over available therapies.

In 2019, 60% of new drug approvals benefited from at least one of the expedited programs. Between 2013 and 2016, 45% of drugs approved under the Breakthrough Therapy program were approved based on a single clinical trial, and 42% were approved based on data from trials without control groups. This has sparked concerns about the lack of quality information available when assessing clinical efficacy, safety, and cost-effectiveness of these drugs.

Many of these drugs receive an orphan drug designation, as they treat conditions that affect fewer than 200,000 individuals in the United States. These drugs may have very high list prices. In 2019, 21 of the 48 novel drug approvals received the orphan drug designation, as did one gene therapy. Of these orphan drugs, nine therapies have an estimated annual cost above $200,000 per patient. Zolgensma®, a gene replacement therapy for spinal muscular atrophy, is now the most expensive FDA-approved therapy in the United States at $2,100,000 for a single treatment. Overall, because utilization is low, these high-cost therapies make up a very low proportion of total Medicaid expenditures. For example, in a national review of Medicaid expenditures from 2018, the top 10 drugs with the highest annual cost per patient ranged from $231,910 to $1,104,165 annually. However, the average contribution to the Medicaid per member per month calculation was only $0.01 to $0.28 across these programs, due to low disease prevalence. In comparison, CMS reports the median annual Medicaid expenditure in 2017 was $8,221 per member, or $685 per member per month. Given the low

disease prevalence, the contribution to the total drug spend for an individual insurer contracted with Medicaid may be harder to predict in the short-term, since the number of members who will need the drug each year and the related costs may vary between plans.

IV. Strategies for Assessing Clinical Criteria for Coverage

Under Section 1927 of the Social Security Act, Medicaid programs are required to cover all FDA-approved drugs that participate in the Medicaid Drug Rebate Program for medically accepted indications. All DMAS MCOs are required to comply with drug coverage as described under the Social Security Act. Although Medicaid is mandated to cover the drugs as above, it may manage the use of some drugs through preferred drug lists, service authorization criteria, and quantity limits. In the context of the federal requirements related to mandatory coverage, the workgroup focused not on whether DMAS should cover certain therapies, but on how to create appropriate clinical standards for FDA fast track drugs and emerging breakthrough technologies, and how to best manage their costs.

Traditionally, healthcare insurance is split into a medical benefit, which covers hospitals, provider visits, and all related therapies and procedures, and a pharmacy benefit, which covers outpatient prescription drug costs. Most assessments of pharmacy expenditures focus specifically on outpatient pharmacy prescriptions, which are paid for under the pharmacy benefit. In recent years, with the increased number of high-cost drugs administered by providers in hospitals or clinics, a new separate category for medical pharmacy has been developed. Medical pharmacy (also known as clinician-administered drugs, or provider-administered drugs) consists of drugs typically covered under the medical benefit, including drugs administered directly by providers. Some insurers may choose to cover these medical pharmacy drugs under the pharmacy benefit along with traditional outpatient pharmacy drugs, though most cover medical pharmacy under the medical benefit.

Before the workgroup meeting, DMAS surveyed all contracted MCOs for their current processes used to create service authorization criteria. In addition, the survey requested recommendations on the scope and structure for a new program, as could be developed by DMAS, to create service authorization criteria for these drugs and technologies. The MCOs' written responses are included in Appendix D.

Current Processes for Service Authorization Criteria Development

DMAS uses separate review processes for traditional pharmacy benefit drugs and those covered under the medical benefit. Under the pharmacy benefit, DMAS maintains a Preferred Drug List (PDL) as a "common core" formulary for all Members enrolled with fee-for-service (FFS) and managed care. The PDL includes drugs in approximately 90 therapeutic drug classes and is developed and maintained by the DMAS Pharmacy and Therapeutics (P&T) Committee. The P&T Committee meets biannually to review the drugs included on the PDL. Historically, only drugs that can be self-administered by the member are subject to the PDL. At a minimum, the MCOs contracted with DMAS must include all preferred drugs on the PDL on their respective formularies and comply with any utilization management controls including any P&T Committee approved clinical criteria for PDL drugs. For non-PDL drugs, clinical coverage requirements may vary by MCO. Because of these contract requirements, all MCOs manage outpatient pharmacy drugs through a similar process to DMAS, including the use of P&T committees to create formularies and utilization management controls. The timeline for this process is typically three to six months for DMAS and most MCOs, and is based in part on the quarterly to biannual meeting schedule for P&T committees.

Medical pharmacy drugs are covered under the medical benefit at DMAS. In the fee-for-service program, DMAS clinical staff determine which drugs require service authorization criteria as new drugs enter the market, engaging external clinical experts and MCOs in the process on a case-by-case basis. A small subset of the most expensive therapies, including Zolgensma®, require a significant level of staff time and resources. The Common Core Formulary does not include medical pharmacy drugs, therefore each MCO currently determines service authorization criteria and formulary status for medical pharmacy drugs separately. Because each MCO develops its own criteria, there is the potential for adverse selection, where a Medicaid member with serious illness seeking coverage for a particular drug chooses the MCO with the least restrictive criteria. With high-cost, low utilization therapies, small changes in enrollment may cause wide variations in average drug expenditures between MCOs.

Current Criteria Development Timeline for Medical Pharmacy Drugs

In the pre-meeting surveys, one MCO mentioned that they use a quarterly committee to develop clinical policy bulletins for drugs and other treatments limited to the medical benefit. Another MCO uses a 'Review at Launch Medication List.' Drugs on this list remain under this policy until the P&T committee can review. Finally, several MCOs mentioned the importance of developing service authorization criteria based on a rigorous review process, including a review of peer-reviewed clinical evidence, the medication's FDA approved indications, available clinical practice guidelines, and discussion with clinician specialists nationally. For most MCOs, the timeline for criteria development for medical pharmacy drugs is three to six months, similar to the timeline for traditional pharmacy, but one MCO also mentioned using a process to accommodate expedited criteria approval, which generally occurs within thirty days if a critical need is established.

Clinical Criteria for Coverage Workgroup

The first of the two workgroup meetings focused on clinical considerations and service authorization criteria for managing Fast Track drugs and emerging technologies. At that meeting, DMAS presented the standards and timelines for the development of service authorization criteria for all drugs managed under the pharmacy and medical benefits utilized by the FFS program (included in Appendix B). Stakeholders were allotted time to comment on their existing process (if one existed) and recommendations for developing standardized criteria.

DMAS also reached out to several other state Medicaid programs in Texas, Nevada and Michigan and presented their models for clinical criteria development. Texas Medicaid was the primary subject for discussion during the workgroup meeting, as that state maintains a Clinician Administered Drug (CAD) Group to manage their medical pharmacy therapies. The group reviews new drugs released throughout the year. If the CADs are determined to be appropriate benefits for Medicaid, then they are presented at a rate hearing as part of the process to become a benefit. Currently, the CAD handbook includes criteria for more than 50 drugs. Texas employs three full-time clinical pharmacists to develop criteria for CADs.

Defining a Subset of Drugs and Technologies

Most stakeholders agreed that the focus should be on FDA fast track drugs and emerging breakthrough therapies, especially orphan drugs and gene therapies. These drugs have low utilization but very high cost, and so a small change in utilization of these drugs may cause outsized fluctuations in the drug expenditures of the MCO reimbursing for them. Without standardized criteria, the stakeholders expressed concern that patients may all choose coverage with the plan utilizing the least restrictive clinical criteria, potentially causing adverse selection and a disproportionate cost burden on a particular MCO. Importantly, the financial implications of any adverse selection are mitigated under the current reimbursement mechanism, which distributes financial risk more evenly among the MCOs.

One stakeholder suggested considering drugs with the highest overall budget impact rather than the annual per-member cost, and another specifically mentioned drugs with mid-level costs but also mid-level impacts. Another factor suggested was focusing on new drugs treating conditions without previous treatment options, as patients would be likely to seek therapy very quickly once the drugs became available. Additionally, it was recommended that DMAS focus on therapies with limited supporting clinical data, for which determining appropriate service authorization criteria may be more difficult and resource intensive. One stakeholder emphasized the importance of careful consideration in developing specific criteria for which drugs should be included in this process, including definitions, and when they should be removed from the list. A cost threshold of $200,000 to $250,000 per member per year was discussed as potentially signifying a high-cost drug, although there was not consensus on this definition.

Developing Service Authorization Criteria

Stakeholders emphasized the value of a collaborative process between DMAS and the MCOs to develop standardized criteria for these drugs. Standardization of criteria across the FFS and managed care populations may assist in preventing adverse selection between plans, which may result under the current system if Medicaid Members choose coverage with the MCO with the least restrictive clinical criteria. One MCO noted that standardization may also assist in preventing provider abrasion, as navigation of coverage for these high-cost drugs may be simpler across plans. Another MCO noted this collaborative process should include both local and national experts, as well as ethicists.

DMAS noted that the recommended collaborative and rigorous process would be resource intensive. The total resources required would depend on the quantity of drugs included in the standardization process. Several MCOs recommended using MCOs proactively as a resource to develop criteria, as they already work with teams across the US and have access to specialists, pharmacists, and other experts. One MCO recommended a collaborative process with all stakeholders present in real-time service authorization criteria creation. Another MCO noted the importance of planning for increased service authorization criteria creation needs in the future, as the number of complex and expensive drugs requiring criteria is likely to increase.

Criteria Development Timeline

Stakeholders agreed on the need to have completed service authorization criteria sooner than the standard three to six months after FDA approval. Several MCOs suggested forecasting new drugs earlier in the process, allowing the review process to begin before the therapies receive FDA approval and reach the market. One MCO noted the example of Zolgensma®, in which physicians requested reimbursement within two months of FDA approval, and the MCO recommended that DMAS develop a process for expedited review. Finally, another MCO noted the importance of maintaining a schedule for future review of drugs on the standardized list, since criteria may require updating based on new FDA approvals and clinical data, and eventually drugs may be removed from the list.

Potential Policy Approaches for Clinical Criteria

Summarized below are potential policy approaches to address the clinical criteria for coverage of relevant fast track drugs and emerging breakthrough therapies.

Policy Approach 1: MCOs continue managing criteria independently

Under this approach, the current system would continue, but perhaps with expedited criteria development for certain therapies. DMAS and the contracted MCOs would separately review and develop clinical criteria for all new drugs not included on the PDL, including all expedited FDA approvals, regardless of cost or fast track status.

Advantages:

1. Administratively, this is the most straightforward model, as it does not require any changes to the current process.
2. No new resources or increased budget would be required for DMAS in this model.
3. This model allows each MCO to manage their own service authorization criteria and formulary to meet the differing needs of their Member population.

Disadvantages:

1. Potential risk for adverse selection to the MCOs with the least restrictive criteria, although the financial consequences would be partially mitigated by the current reimbursement model.
2. Provider and member abrasion dealing with multiple criteria sets.

Policy Approach 2: DMAS creates and manages standardized criteria

Under this approach DMAS would develop and manage standardized criteria in a process similar to the current development for drugs included on the PDL/common core formulary. DMAS would need to either hire additional staff for internal review or contract with an outside vendor for this process. The MCOs would then be required to adopt and comply with the DMAS published clinical criteria for medical pharmacy drugs.

Advantages:

1. Administratively, a similar process for dissemination and implementation of standardized criteria already exists between DMAS and the MCOs for drugs on the PDL. The process for clinical criteria development of fast track drugs and emerging breakthrough technologies could be modeled after the PDL process.
2. This process may prevent adverse selection between MCOs, as all MCOs would use the same clinical criteria.
3. This process may reduce provider abrasion for these therapies, as clinical criteria and service authorization requirements would be standard across MCOs.

Disadvantages

1. This plan would require additional appropriation to DMAS. New full-time equivalent positions, including additional physicians, pharmacists, epidemiologists, and others may need to be hired or contracted to conduct criteria development, depending on the number of therapies included in this process.
2. In this approach, the MCOs have minimal control over how criteria are created for each included therapy. There would be limited ability to modify criteria to fit a unique Member population within a given MCO.

Policy Approach 3: DMAS and MCOs collaboratively create standardized clinical criteria

Under this approach, DMAS and the contracted MCOs would work collaboratively to create standardized criteria for included therapies.

Advantages:

1. All stakeholders would have the opportunity to contribute to the development of clinical standards and represent any unique needs of their Member populations when doing so.
2. This approach would leverage resources from the MCOs, and therefore would likely have lower budget impact than Policy Approach 2.
3. This process may prevent adverse selection between MCO plans, as all MCOs would use the same clinical criteria.
4. This process may prevent provider abrasion for these therapies, as clinical criteria and service authorization requirements would be standard across MCO plans.

Disadvantages:

1. Administratively, this plan is likely to be the most complicated, as it will require the development of an ongoing collaborative process between at least 7 organizations (DMAS and the MCOs) for which we do not currently have a model. This will require time and attention from many more individuals than any other process.
2. This approach will likely still require moderate budget changes including the addition of new full-time equivalent positions, but perhaps a lower amount than approach 2. Though fewer clinician hours would be provided by DMAS for this approach, substantial administrative hours would likely still be required, and may not be available with current staffing.
3. There would be limited ability to modify criteria to fit a unique Member population within a given MCO.

V. Strategies for Addressing Risk Sharing and Reimbursement Methodologies

The second workgroup meeting focused on financial considerations including risk sharing arrangements and reimbursement methodologies. At that meeting, DMAS presented five risk mitigation models for the workgroup's consideration. The workgroup reviewed the stakeholder responses to the question of how DMAS should reimburse for high-cost, low-utilization therapies. A summary of the main provisions for each model was reviewed as well as the advantages and disadvantages of each model. The workgroup also reviewed the models currently being utilized in New York, California, Maryland, Washington DC and a number of other states.

The five risk mitigation models examined are as follows:

1. Risk Pool (Current Approach)
2. Partial Carve-out
3. Risk Corridor
4. Kick Payments
5. Individual Reinsurance or Stop-Loss

Risk Mitigation Models

Model 1: Risk Pool (Current Approach since 2018)

This is the agency's current risk mitigation model. Estimates of both cost and utilization for new high-cost, low-utilization drugs are made for each program using the best information available in the months prior to the start of each contract period. Projected costs are then allocated by program, region and rate cell based on the expected parameters of FDA approval and anticipated place in therapy for each drug.

Pharmacy trend development is analyzed by Therapeutic Classes (TCs). TCs are segregated by traditional and specialty, with each analyzed separately and in aggregate by program. Drug specific pharmacy trends are not established due to the volatile and unpredictable nature of costs at the drug level of detail. Additional adjustments are typically made in the rate development to account for potential utilization above and beyond what is included in pharmacy trend development for gene therapies and other high-cost drug products. For example, specific rate adjustments were made for pipeline Hemophilia gene therapy products and Zolgensma® in previous years. If the actual cost and utilization of these new therapies differ from what was built into the capitation rates of the MCOs, the MCOs would bear the financial loss or reap the financial gain during the contract period.

A risk pool is then utilized to spread cost of high-cost, low-utilization (HCLU) therapies over all MCOs. Because of the high cost and low utilization of certain drugs, there is an elevated financial risk for an individual MCO that receives a disproportionate share of these claims during a given contract period. In the case of extraordinarily costly drugs such as Zolgensma®, a single MCO may get one or two claims in a single contract period while another MCO has none, creating a $2 million to $4 million swing in expenses. In this scenario, these claims would be subject to DMAS' Pharmacy Reinsurance Risk Pool, which serves to mitigate (but not eliminate) the risk that a given MCO would be financially advantaged in a period where they incur disproportionately fewer claims for new HCLU drugs. The opposite is true for the MCO incurring disproportionately more claims for new HCLU drugs, leading to a disadvantage. In the case of a $2 million drug for MCO A, under the current model, MCO A would pay $357,000 ($175,000+.1*($2,000,000 - $175,000)). The remaining $1,643,000 would be allocated to all participating MCOs based on Medicaid revenue. Reinsurance pools are designed to spread the risk associated with high cost claimants among all of the participating MCOs thereby ensuring that no single MCO is financially advantaged or disadvantaged. The use of a reinsurance pool does not shift risk from the MCOs to the Medicaid agency, rather, it more equitably distributes that risk among the participating MCOs.

Under this strategy, there would be no change to the risk being assumed by DMAS by definition.

Advantages

1. Administratively, this is the most straightforward model as it does not require any changes to the current rate-setting or risk adjustment processes.
2. DMAS maintains budget predictability as the risk for unpredicted price or utilization remains with the MCOs.
3. This financial arrangement maximizes the MCOs' incentive to effectively and efficiently manage utilization and prices for these new drugs and therapies.

Disadvantages

1. This approach requires the Agency's actuary (Mercer) to forecast drug cost and utilization estimates with minimal pricing data in certain instances.
2. While the Pharmacy Reinsurance Pool will eventually address disparities in MCO costs based on which plans get more or fewer HCLU drug claims, it does not address potential cash flow issues. Specifically, it is usually several months after the contract period has concluded before the Pharmacy Reinsurance Pool is evaluated and settled.

Model 2: Partial Carve-Out

Under this model, DMAS would work with its actuary and the MCOs to evaluate new HCLU drugs as they come to market. Drugs that meet established criteria would be carved out of the MCO capitation rates and covered by DMAS on a fee-for-service (FFS) basis for a short time period. DMAS and its actuary would then periodically review utilization and pricing for

all drugs that are carved out of rates to determine if and when there is sufficient volume and stability in the FFS experience to allow for these drugs to be carved back into MCO capitation rates.

With respect to capitation rates, drugs would need to be excluded from base experience and trend projections based on when they are carved out of capitation rates. The opposite would occur when drugs are carved back into capitation rates. Additionally, DMAS' risk adjustment methodology would need to be reviewed and possibly adjusted more frequently than current standards to ensure proper alignment with the carve-out list.

Under this model, the key point is that DMAS is assuming all pricing and utilization risk associated with the drugs and therapies that are carved out of capitation rates. Furthermore, there are few, if any, models at DMAS' disposal for limiting exposure to this budget risk in any individual contract period outside of reducing the number of drugs that are carved out during a given contract period.

Advantages

1. This model addresses MCO concerns regarding both the allocation of HCLU drugs across MCOs as well as the overall pricing risk related to HCLU drugs.
2. Administratively speaking, it is relatively straightforward to implement operationally (with one notable exception, which is discussed below).
3. Eliminates the need for DMAS and its actuary to forecast cost and utilization estimates with limited drug price data prior to each contract period.

Disadvantages

1. This strategy is inconsistent with the concept of integrated, whole person care under a single delivery system. In particular, DMAS would need to establish data and information sharing protocols between its FFS program and the MCOs so that the MCOs know when one of their members has received a drug that has been carved out of capitation rates.
2. DMAS loses the budget predictability under this model relative to the status quo. This model also creates a need for DMAS to maintain and forecast a new "HCLU Drug" budget line each year.
3. Objective HCLU criteria would need to be specified and a drug list maintained. Based on similar policies in other states, criteria development would require additional staffing and appropriations.
4. Under this model, the MCOs retain little to no financial incentive to efficiently and effectively manage the utilization of new high-cost, low-utilization drugs.
5. DMAS' models for capping its exposure in any given contract period are limited.
6. To the extent that drugs administered in an outpatient hospital setting are included on the HCLU drug list, it may present a challenge due to the lack of an outlier payment in DMAS' FFS outpatient hospital payment methodology. DMAS would likely need the authority to implement a drug outlier payment in their FFS outpatient hospital reimbursement methodology in order to ensure that providers are reimbursed adequately for any such claims. Differences in reimbursement levels for 340B pharmacy providers between the FFS program and the MCOs may need to be addressed in a similar fashion.

Model 3: Drug Risk Corridor

Under this model, high-cost new therapies would continue to be covered through the regular Medallion and CCC Plus capitation rates; however, drugs that meet established criteria would be subject to a risk corridor. The MCOs would then be responsible for managing and paying these claims as they arise; however, settlement payments from the risk corridor would mitigate the financial risk associated with an MCO experiencing more high-cost, low-utilization drug claims than estimated by DMAS and its actuary. A risk corridor also simultaneously protects DMAS against the risk of overpricing of HCLU drugs in capitation rates. Additionally, the corridor could be evaluated on a quarterly, semi-annual or annual basis, depending on DMAS' preference, as a mechanism for addressing cash flow concerns.

Similar to the partial carve-out model, new HCLU drugs would need to be evaluated as they come to market to determine whether or not they meet the established criteria to be subject to the risk corridor. DMAS and its actuary would then periodically review utilization and pricing for all drugs that are carved out of rates to determine when there is sufficient

volume and stability in the MCO experience so as to justify removing them from the risk corridor. Additionally, capitation rate-setting and risk adjustment methodologies would remain generally unchanged from the status quo under this model.

Under this model, some of the pricing risk associated with the drugs/therapies that are included in the risk corridor would shift from the MCOs back to DMAS relative to the status quo. That being said, this model provides DMAS with more flexibility in terms of limiting its exposure through strategic design of the risk corridor as compared to a partial carve out.

Advantages

1. This strategy preserves the integrated single delivery system for members.
2. Under this model, the MCOs retain a financial incentive to efficiently and effectively manage the utilization of new high cost, low utilization drugs.
3. Although DMAS is assuming pricing risk under this scenario that is the responsibility of the MCOs under the status quo, DMAS has considerably more flexibility with respect to sharing or capping its exposure to this risk relative to the partial carve out.

Disadvantages

1. DMAS loses some budget predictability under this model relative to the status quo. This model also creates a need for DMAS to maintain and forecast a new "HCLU Drug Risk Corridor Settlement" budget line each year.
2. Objective HCLU criteria would need to be specified and a drug list maintained. Based on similar policies in other states, criteria development would require additional staffing and appropriations.
3. Among the models presented here, the risk corridor is likely to be the most complex to administer.

Model 4: Kick Payments

Under this model, DMAS would work with its actuary and the MCOs to evaluate HCLU drugs as they come to market. Drugs that meet established criteria would be excluded from the MCO capitation rate development and covered by DMAS through a kick payment. DMAS would periodically analyze the prescription drug encounters (including those administered in an inpatient or outpatient setting) submitted to the encounter processing system (EPS). Any encounter records for drugs that meet the established criteria would trigger a kick payment to the MCO. Mercer would estimate the cost of new HCLU drugs for each program using the best information available as of a few months prior to the start of each contract period. The amount of the kick payment would be based on these estimates. Mercer would periodically review utilization and pricing for the drugs that are subject to a kick payment to determine when there is sufficient volume and stability in the experience to allow for these drugs to be included back into the monthly MCO capitation rates.

With respect to capitation rates, drugs would need to be excluded from base experience and trend projections based on when they are included as kick payments, and included again once the drugs are added back to capitation rates. Additionally, DMAS' risk adjustment methodology would need to be reviewed and possibly adjusted more frequently than current standards to ensure proper alignment.

Under this model, DMAS is assuming all of the utilization risk associated with the drugs and therapies that are subject to the kick payment method. The pricing risk would be symmetrical, with DMAS benefiting when the kick payment pricing was inadequate and MCOs benefiting if they manage to negotiate lower pricing then that assumed in the kick payment development.

Advantages

1. This model addresses MCO concerns regarding both the allocation of HCLU drugs across MCOs as well as the utilization risk related to HCLU drugs.
2. Administratively speaking, it is relatively straightforward to implement operationally.

Disadvantages

1. DMAS loses the budget predictability under this model relative to the status quo. This model also creates a need for DMAS to maintain and forecast a new "Pharmacy Kick Payment" budget line each year.
2. Objective HCLU criteria would need to be specified and a drug list maintained. Based on similar policies in other states, criteria development would require additional staffing and appropriations.
3. Under this model, the MCOs retain little to no financial incentive to efficiently and effectively manage the utilization of new HCLU drugs.
4. DMAS' models for capping its exposure in any given contract period are somewhat limited.

Model 5: Individual Reinsurance

This was the approach utilized by DMAS from 2013 through 2018, prior to adoption of the risk pool approach. The approach was discontinued after 2018 due to the lack of budget predictability as noted below. Under this model, DMAS would provide reinsurance on pharmacy claims for any member whose annual prescription drug costs exceed a chosen attachment point. The attachment point is chosen based on information on high cost drugs that are in the pipeline and overall level of risk that the MCOs are willing to accept. Typical attachment points are $100,000, $150,000, $250.000 etc. A percentage of prescription drug costs in excess of the attachment point would be covered by DMAS. This percentage can vary from a 50/50 split up to a 90/10 split with MCOs responsible for 10% of costs in excess of the attachment point. DMAS would work with Mercer and the MCOs to evaluate an appropriate attachment point as well as the percentage reinsured. Using the design parameters, Mercer would then determine an appropriate premium to cover the projected reinsurance claims with such premium being subtracted from the capitation rate otherwise paid. On a quarterly basis, the encounter data submitted by the MCOs would be analyzed to determine the aggregate dollar amount of reinsurance claims each MCO incurred. DMAS would reimburse the MCOs quarterly for the aggregate amount of pharmacy reinsurance claims.

Potential change to DMAS' exposure: under this model, DMAS is assuming a large portion of the price and utilization risk associated with the reinsured drugs/therapies in a given contract period. The pricing and utilization risk would be symmetrical with DMAS benefiting when the reinsurance pricing and utilization assumed in the reinsurance premium was adequate. DMAS would suffer losses if the reinsurance claims exceed the amount of reinsurance premium subtracted from the capitation rates.

Over the long term, we would generally expect this model to be budget neutral. That is, the reduction in capitation revenue from the reinsurance premium should be sufficient to cover the aggregate pharmacy reinsurance payments.

Advantages

1. Does not require objective "HCLU Drug" criteria to be specified.
2. This financing arrangement partially preserves the MCOs' incentive to effectively and efficiently manage utilization and prices for these new drugs/therapies.
3. Administratively speaking, it is relatively straightforward to implement but requires quarterly reporting and payment mechanisms.
4. Gives MCOs risk protection and results in lower per capita variability in MCO pharmacy expenditures.

Disadvantages

1. DMAS loses budget predictability within a given year under this model relative to the status quo.
2. Requires that Mercer (in conjunction with DMAS) forecast pharmacy reinsurance claims and calculate a reinsurance premium each contract period.
3. Under this model, the MCOs retain some financial incentive to efficiently and effectively manage the utilization of new HCLU drugs, but most of the pricing and utilization risk is borne by DMAS.

MCO Comments on Reimbursement

Prior to the second workgroup meeting, written stakeholder comments were solicited on financial considerations for fast-track drugs and emerging breakthrough technologies. These comments are included in Appendix D – MCO Comments on High Cost Low Utilization Drug Reimbursement.

Following the second workgroup meeting, the MCOs met with the Virginia Association of Health Plans and collaboratively discussed the reimbursement methods presented at the workgroup meeting. The MCOs were able to reach a consensus as to their preference for the individual reinsurance methodology (Model 5), which had been in effect at DMAS between 2013 and 2018.

Review of Other State Medicaid Programs

- The workgroup reviewed the chart included as Appendix C - High Cost Drug Risk Mitigation Strategies by State. It should be noted that several states utilize more than one model for risk mitigation. Florida, Louisiana, Nebraska, Ohio and Virginia utilize the risk pool model.
- California, New York, Indiana, Maryland, Michigan, Mississippi, Nevada, Oregon, Ohio, Utah, Washington DC, West Virginia, Iowa and New Hampshire all partially or completely carve-out prescription drug coverage from their managed care contracts.
- Louisiana, Massachusetts, Nevada, New Jersey, New Mexico and Kentucky use the risk corridor model.
- California, Mississippi, South Carolina, Kansas and Washington use a pharmacy kick payment approach for certain drugs such as Zolgensma® or hepatitis C drugs.
- Arizona, Delaware, Pennsylvania and Rhode Island utilize the pharmacy reinsurance or stop-loss approach.

Clinical Meeting Participants – August, 25, 2020

Adrienne Fegans	Deb Stephens	Josh Humphries	Paul Gibney
Andrew Mitchell	Donna Proffitt	Karen Thomas	Rachel Cain
Andrew Ramsey	Doug Gray	Karla Callaham	Randy Ricker
Ann Vaughters	Jason Rachel	Kenneth McCabe	Rob Berringer
Bill Lessard	Jennie Reynolds	Kristi Fowler	Robert Coalson
Catherine Brisland	Jerry Mammano	Mark Mattingly	Sarah Samick
Cheryl Roberts	Jessica Annecchini	Mike Fotinos	Sericka McGee
Chethan Bachireddy	Jessica Daw	Mike Tweedy	Tamara Whitlock
Chris Gordon	Joe Kupiec	Mohamed Ally	Thomas Gates
Daniel Plain	John Stanwix	Nettie Emmelhainz	Timothy Merciez

Financial Meeting Participants – September 1, 2020

Adrienne Fegans	Doug Gray	Katherine Long	Rob Berringer
Alexandra Lee	Emily Anderson	Kenneth McCabe	Sara Drake
Andrew Mitchell	Felicia Hemby	Kristi Fowler	Scott Cannady
Andrew Ramsey	Ira Bloomfield	Kristin Mincer	Sericka McGee
Ann Vaughter	James Jullerat	Linda Hines	Shane Wimalendran
Bertrand Ross	Jason Rachel	Mark Blessinger	Steve Whitehead
Bhanusree Kosuri	Jennie Reynolds	Mark Mattingly	Tameeke Smith
Bill Lessard	Jessica Annecchini	Michael Fotinos	Tammy Whitlock
Bob Coalson	Jessica Daw	Mike Tweedy	Tarshema McLemore
Cheryl MacMillan	Joe Kupeic	Mohammed Ally	Tim Carpenter
Cheryl Roberts	John Muraca	Nettie Emmelhainz	Todd Raithal
Chethan Bachireddy	John Stanwix	Nick Mercier	
Deb Stevens	Josh Humphries	Paul Gibney	
Derrick Lee	Karen Thomas	Rachel Cain	
Donna Proffitt	Karl	Randy Ricker	

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

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.

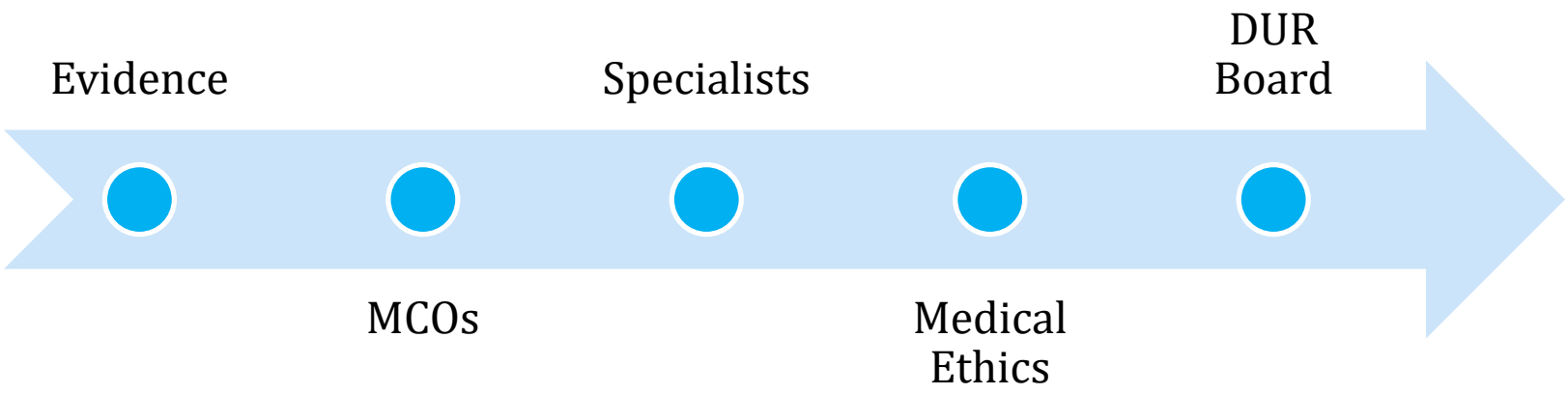
Other Medicaid Programs Clinical Criteria Process for Pharmacy Benefit Covered Drugs

- **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?

Risk Mitigation Strategies for High Cost Drugs

August 2020

Medicaid agencies around the country are challenged to develop clinical policies and reimbursement mechanisms for high-cost drugs used to treat relatively small segments of their covered populations. The majority of managed care Medicaid programs carve in their pharmacy services for the managed care organization (MCO) enrollees, although some have carve outs for certain high-cost drugs or select drug classes (e.g., HIV/AIDS drugs, hepatitis C medications, hemophilia, etc.). Various high-cost drug-financing options are available for Medicaid managed care programs. These options may be specifically limited to drugs in the pharmacy benefit, or may be expanded to include drugs costs reflected in the medical benefit. States may use one or a combination of the following strategies:

Option 1	States Currently Using Model (Not An Exhaustive List)
Risk Pools (Budget Neutral)	
A mandatory "premium" is applied to all plans through a capitation rate reduction that funds the risk pool arrangement. Then, based on actual, allowable expenditures, the risk pool is distributed amongst the plans based on the terms and conditions of the risk pool. Premium may not need to actually be deducted from rates if factored into the settlement process when the risk pool is distributed among the plans.	**Florida** operates a risk pool for hepatitis C in their Title 19 population. **Louisiana** operates a risk pool for Zolgensma® that is funded based on projected utilization and redistributed proportionally to the plans based on actual Zolgensma utilization. **New York** operates a high-cost Rx risk pool for hepatitis C drugs that redistributes between all the health plans a set amount of funds based on the actual expenditures for the eligible drugs. **Virginia** currently utilizes a risk pool; previously utilized a reinsurance arrangement. **Additional states** as self-identified in the 2020 KFF Survey[1]: NE, OH.

[1] https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-introduction/

Option 2	States Currently Using Model (Not An Exhaustive List)
Carve-Outs (Full Or Partial)	
The specific population or service is removed from the risk-based managed care program and provided through a different delivery system (often fee-for-service [FFS]).	**California** carves-out HIV/AIDS drugs and psychotropic medications[2] as well as blood factor products. A full carve-out of the pharmacy benefit to FFS will take effect January 2021. **Florida** carves out hemophilia drugs.[3] **Indiana, Missouri, Nebraska, Tennessee and Wisconsin** carve-out all pharmacy from managed care.[4] **Maryland** carves out substance use disorder drugs, HIV/AIDS medications and some mental health drugs.[5] **Michigan** carves out a number of drug categories that include HIV, hepatitis C, hemophilia and mental health drugs.[6] **Mississippi** carves out hemophilia factor products from managed care[7]. **Nevada** carves out Zolgensma from the managed care contracts. **New York** plans a full carve-out of the pharmacy benefit to FFS on April 1, 2021.[8] **Ohio** has been directed by the legislature to move toward a carve-out to FFS or a single PBM model.[9] **Oregon** carves out behavioral health drugs.[10] **Utah** carves out all hemophilia treatment drugs, immunosuppressants used for organ transplants and mental health drugs from its accountable care organization contracts.[11] **Washington, D.C** carves out HIV drugs, with the exception of drugs used for Pre-exposure Prophylaxis (PrEP). Although the HIV population will be carved-in to managed care effective October 1, 2020, HIV drugs will continue to be carved-out. **West Virginia** carved the entire pharmacy benefit out of managed care on July 1, 2017.[12] **Additional states** as self-identified in the 2020 KFF Survey:[13] IA, NH.

[2] California Department of Health Care Services, Medi-Cal Managed Care Boilerplate Contracts viewable at: http://www.dhcs.ca.gov/provgovpart/Pages/MMCDBoilerplateContracts.aspx
[3] Florida Medicaid Hemophilia Coverage Page viewable at: http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Quality/fee-for-service/hemophilia.shtml
[4] https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf
[5] Kaiser/NAMD Ibid
[6] State of Michigan Medicaid Pharmacy Carve-Out List page viewable at: https://michigan.fhsc.com/Downloads/MI_MedicaidHealthPlanCarveout.pdf
[7] https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-appendix/
[8] https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/pharm_carve_out_faq.pdf
[9] https://www.legislature.ohio.gov/legislation/legislation-status?id=GA133-HB-166
[10] https://www.oregon.gov/oha/HSD/OHP/Pages/Policy-OHP.aspx
[11] https://medicaid.utah.gov/pharmacy/accountable-care-organizations
[12] https://dhhr.wv.gov/bms/News/Documents/WV%20BMS%20Rx%20Savings%20Report%202019-04-02%20-%20FINAL.pdf
[13] See footnote 1.

Option 3	States Currently Using Model (Not An Exhaustive List)
Risk Corridors	
Risk corridor mechanisms establish a corridor around a target expense ratio, and risk is shared if expenses fall above or below the corridor.	**Louisiana** utilizes a risk corridor for hepatitis C-related pharmacy, physician and laboratory costs.[14] **Massachusetts** utilizes a risk corridor for hepatitis C, hemophilia, cystic fibrosis, spinal muscular atrophy and other high-cost drugs meeting an established high cost and low prevalence threshold. **Nevada** utilizes a risk corridor for a comprehensive list of specialty drugs. **New Jersey** utilizes a risk corridor for high cost, low prevalence drugs. **New Mexico** utilizes a risk corridor for hepatitis C drugs under its Centennial Care contracts.[15] **Additional states** as self-identified in the 2020 KFF Survey[16]: HI, KY, NE, OR, RI.

Option 4	States Currently Using Model (Not An Exhaustive List)
Supplemental "Kick" Payments	
The cost of the targeted service is removed from the monthly capitation rates and incorporated into a separate payment arrangement, similar to a supplemental maternity care payment process.	**California** provides monthly supplemental kick payments for hepatitis C paid to the MCOs based on a weekly rate developed through the MCOs' data submissions. A full carve-out of pharmacy benefit to FFS will take effect January 2021. **Mississippi** reimburses MCOs for the cost of Zolgensma. **South Carolina** reimburses MCOs for the cost of drugs included in the Pharmacy Risk Mitigation program. Payment is limited to the reimbursement rate for FFS coverage. **Washington** reimburses MCOs for the encounter cost of all drugs paid for through the pharmacy benefit. While MCOs are at risk for most physician-administered drugs, very high cost drugs are excluded from capitation when not administered in an inpatient setting, including Zolgensma, Luxturna®, CAR-T and hemophilia products. **Additional states** as self-identified in the 2020 KFF Survey[17]: KS, MD, MI.

[14] https://ldh.la.gov/assets/docs/BayouHealth/MercerRateLetters/healthylouisianaexpansioncapitationratescertificationeffectiveJul2019-dec2019.pdf
[15] New Mexico Centennial Care Model Contract, Amendment #4 viewable at http://www.hsd.state.nm.us/LookingForInformation/medical-assistance-division.aspx
[16] See footnote 1.
[17] See footnote 1.

Option 5	States Currently Using Model (Not An Exhaustive List)
Risk-Sharing	
A mandatory "premium" is applied to all plans through a capitation rate reduction that funds the risk-sharing arrangement. Then, based on actual, allowable expenditures, plans are reimbursed via the terms and conditions of the risk-sharing arrangement. Similar to a reinsurance policy purchased on the open market.	**Arizona** keeps drugs for hemophilia, von Willebrand's disease, and Gaucher's disease carved in, but partially covers them with catastrophic reinsurance.[18] **Delaware** maintains a list of high-cost drugs that are eligible for the risk-sharing program. Once the list is set, 80% of the amount built into the rates for these drugs is withheld (paper withhold) from the rates. Each quarter, the plans submit all eligible claims for the listed drugs, and the state pays (or collects) the difference after the withheld amount is removed. **Pennsylvania** uses a risk-sharing arrangement for cystic fibrosis that is funded with a percent of the total cystic fibrosis dollars built into the capitation rates. **Rhode Island** uses stop-loss payments for its managed care plans for hepatitis C drugs.[19]

[18] Arizona Health Care Cost Containment System (AHCCCS) Acute Care Contract Amendments viewable at https://www.azahcccs.gov/Resources/OversightOfHealthPlans/SolicitationsAndContracts/contracts.html
[19] Kaiser/NAMD ibid

Appendix D

MCO Comments on High Cost Low Utilization Drug Reimbursement

Prior to the workgroup meetings, DMAS requested the MCOs consider and respond to the following questions:

- How does your organization develop criteria for these drugs and technologies?
    - In which ways is the process for developing criteria for these drugs and technologies different from processes for non-FDA fast-track/breakthrough drugs and technologies, if any?
    - On average, how long does it take?
    - Who is usually involved?
- For each of the three questions below, please indicate: 1) your recommendation for the Virginia Medicaid program, including reasons for your recommendation, and 2) anticipated implications for Medicaid members, MCOs, DMAS, and the state
    - To what extent should DMAS and the MCOs focus on the drugs and technologies highlighted in the GA budget language vs a different subset of drugs and technologies (if a different subset, please define what that different subset should be)?
    - How should DMAS develop criteria for these drugs?
    - How should DMAS reimburse for these drugs?

Shown below are the MCOs' written comments on financial considerations for fast-track drugs and emerging breakthrough technologies submitted to DMAS prior to the workgroup meeting. Comments were lightly edited for brevity and clarity.

MCO 1: A kick payment methodology is virtually the only way to properly reimburse MCOs for the risks related to high cost specialty drugs, for the following two reasons:

- Due to the low frequency and high severity nature of high cost specialty drugs, it is very difficult to properly project the risk exposure even for the entire program, in addition to meeting the CMS actuarial soundness requirement at each rate cell level. This issue is particularly true for new drugs with no credible experience.
- The same is more true with respect to MCO reimbursement. Risk adjustment doesn't solve the problem because the past experience is not predictive of future experience and therefore does not fit the prospective risk adjustment methodology.

MCO 2: We would encourage DMAS to reimburse these drugs through a kick payment vehicle until there is enough experience to incorporate the impact into the base rate data in developing actuarially sound rates.

MCO 3: We believe that the utilization of these drugs & technologies will be generally unpredictable and will thus be difficult to include in any capitation rate development. However, there should be some general predictability as to the cost. Thus, the most effective means for reimbursing the MCOs will be via a Kick payment. Under that model, each MCO would be reimbursed a defined amount for each script issued for each of these drugs & technologies.

MCO 4: The recommendation regarding reimbursement is to continue the current payment model with risk pool sharing among the MCOs.

Appendix D

MCO Comments on High Cost Low Utilization Drug Reimbursement

MCO 5: We would like to see a threshold of cost that initiates reinsurance, which was in place previously. So, for therapies that exceed a certain threshold, *i.e.*, $175,000, DMAS would pay 90% and the MCO would be responsible for the other 10%. Risk pools adversely benefit larger MCOs with larger membership. Whereas a smaller MCO would be paying more to assist in coverage for the other large MCOs. Using this methodology would afford members more access to life saving therapies and more appropriately distribute the financial burden.

MCO 6: The addition of emerging high-cost Fast Track drugs and Emerging Technology / Treatments to the risk pool serves to reallocate capitation among payers based on their share of incurred costs. This may ensure that no single payer is affected disproportionately. Potential improvements to this method may arise from such factors as:

- Varying definitions of qualified expense (>$100K per member or per treatment episode? Or drug/class level definition – all costs for a selected class?)
- Treatments/drugs which meet the established criteria would flow on to non-risk (pass-through) for payers for an initial study period (*e.g.* 2-3 years).
- Following the initial 'study' period, drugs/treatments are returned to inclusion in the at-risk capitation.
- For members, this method supports continuity of coverage (unlike a full carve-out) and may reduce delays in treatment.
- For MCOs, this method more evenly manages financial risk.
- For DMAS, this method simplifies oversight and timely management of high-cost Rx/treatment utilization. It also allows the DMAS actuaries to gather baseline data for improved accuracy in future rate setting.
- For Virginia, this method reduces administrative burdens on prescribers, improves treatment efficiency and may improve treatment outcomes and productivity of Virginians.

Our organization urges DMAS to consider revisiting the logic and rules for participation in the current high-cost drug risk pool program. Under the current identification rules, the medication costs for Medicaid managed care enrollees whose single medication treatment costs exceed $175k/year are pooled between all MCOs. The key point to note is that this additional funding pool works because the pharmacy benefit is adequately funded in total. If breakthrough drugs are not adequately considered in the pharmacy development, the pool simply results in the underfunding being spread across all MCOs. One approach our pharmacy management and actuarial colleagues recommend to correct this may be to add a kick payment for drugs that are very high cost/low frequency, such as Zolgensma, as a small variation in number of cases could quickly cause the pool to be underfunded.

Emerging technologies that are not drugs, should be considered in Mercer's rate development. Rate development for the current year did not anticipate new technologies being fast tracked, so an adjustment would need to be made. Like with high-cost medications, if certain cases are very high cost/low frequency, a kick payment or other risk sharing arrangement may prove to be both pragmatic and appropriate.