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## MASSHEALTH (MEDICAID)

Re: 1115 Waiver Amendment is being considered that would 1) create a closed formulary, thereby allowing the state to exclude coverage of any drugs not on the formulary, and 2) exclude those drugs from the formulary that the state considers to have limited or inadequate evidence of clinical efficacy

## EXECUTIVE SUMMARY

MassHealth is requesting a 1115 waiver to implement a closed formulary that would contain at least one drug per therapeutic category. The closed formulary would allow for an exceptions process, similar to the one they now use for new-to-market drugs, for non-formulary drugs. The exceptions process referred to currently denies coverage during the internal review period. The amendment is also asking for the ability to exclude drugs from the state's primary formulary that have been approved through the FDA's accelerated pathway with limited or inadequate clinical efficacy, as determined by the state's own internal review. Note the use of the word primary. This infers that this would be outside of the closed formulary process and would not have access to an exception process.

## BACKGROUND

Massachusetts Medicaid 1115 waiver was initially established in 1995. It was recently renewed on July 1, 2017, and is renewed through June 30, 2022. The extension provides Massachusetts the support to move forward with implementing Accountable Care Organizations (ACOs). On September 8, 2017, MassHealth submitted to CMS the MassHealth Section 1115 Demonstration Amendment Request, which includes the language described in the above paragraph.

## CLOSED FORMULARY

The below paragraphs are taken directly from the 1115 Waiver. Artia has underlined a few notable phrases. The Waiver can be accessed through the resources at the end of this document.

**Adopting widely-used commercial tools to obtain lower drug prices and enhanced rebates**

- Select preferred and covered drugs through a closed formulary that assures robust access to medically necessary drugs
    - **Adopt a commercial-style closed formulary with at least one drug available per therapeutic class**

Adopting a closed formulary with at least a single drug per therapeutic class would enable MassHealth to negotiate more favorable rebate agreements with manufacturers. For each therapeutic class, the state could offer manufacturers an essentially guaranteed volume in exchange for a larger rebate. (Page 8)

*Exceptions Process:* In selecting drugs available in each therapeutic class, MassHealth will ensure that the selected drugs meet the clinical needs of the vast majority of members and that they are cost effective. In addition, MassHealth will maintain an exceptions process to cover drugs that are not on the formulary when medically necessary, including but not limited to exceptions to address adverse drug reactions, drug interactions, or specific clinical needs of a patient. The exceptions process will be similar to the existing clinical review process used for situations such as determining coverage of non-preferred products or off-label indications.

MassHealth's review process for all drugs includes a careful assessment of clinical trial results, published literature, guideline consensus, comparisons with other related drugs, modeling of the expected patient populations who would benefit from the drug, and coverage by other payers. (Page 9)

- **Excluding drugs from formulary that have limited or inadequate evidence of clinical efficacy**

Many drugs coming to market through the FDA's accelerated approval pathway have not yet demonstrated clinical benefit and have been studied in clinical trials using only surrogate endpoints. Massachusetts seeks the ability to use its own rigorous review process, in partnership with the University of Massachusetts Medical School, to determine coverage of new drugs and to guarantee that patients access clinically-proven, efficacious drugs. Through this process, the state could avoid exorbitant spending on high-cost drugs that are not medically necessary. The 21st Century Cures Act was intended to expedite the drug approval process by reducing the level of evidence required for drugs to reach the market and allowing doctors, patients, and payers to decide whether to purchase them. Unfortunately, current rules do not allow Medicaid programs to exercise discretion about whether these drugs should be covered without being fully clinically proven.

MassHealth proposes to utilize the flexibility granted under the waiver to exclude drugs with limited or inadequate clinical efficacy from its primary formulary. Limited or inadequate clinical efficacy may be defined as when one or more of the following conditions exist:

- Primary endpoints in clinical trials have not been achieved;
- Only surrogate endpoints have been reported;
- Clinical benefits have not been assessed;
- The drug provides no incremental clinical benefit within its therapeutic class, compared to existing alternatives.

Members would continue to have access to the latest drugs that provide proven additional clinical benefits. Whenever a new drug is proven to have incremental clinical value relative to peer drugs in its therapeutic class, it would be covered. In addition, breakthrough drugs with proven clinical benefit in new therapeutic classes would be covered. Only in cases where the incremental clinical benefit is undemonstrated would the state consider excluding a drug from its standard formulary. Members could still request coverage of non-formulary drugs, using the exceptions process as described above. (Pages 9-10)

## RESOURCES

MassHealth Section 1115 Demonstration Amendment Request

MassHealth and State Health Care Reform

MassHealth Supplemental Rebate/Preferred Drug List

## CONSIDERATIONS FROM THE ARTIA TEAM

1. MassHealth already has a PDL which they have been slow to implement. They currently only review three therapeutic categories as compared to other state Medicaids that review 60+ therapeutic categories.

2. Doesn't the current PDL process allow MassHealth to limit to one drug in a category if that's what they decide from a financial, clinical, and safety basis?

3. There is nothing limiting them now to agreeing to market-share language in the current PDL bid process.

4. Hasn't there already been numerous studies on restrictions to medications for Vulnerable Patients that have proven to be counter-productive and risky, thereby not qualifying for an "experimental, pilot, or demonstration project?"

5. Wasn't one of the premises to the FDA accelerated review to provide earlier access to these medications rather than increasing delays?