

Louisiana Medicaid
~~Oral~~ Immunosuppressives, Oral

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred oral immunosuppressives.

Additional Point-of-Sale edits may apply.

*~~NOTE: Some of these agents medications in this therapeutic category~~ may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Initial and Reauthorization Requests ~~for Non-Preferred Oral~~ Immunosuppressives

- For sirolimus oral solution (generic for Rapamune®) - there has been a treatment failure or intolerable side effect with or contraindication to brand Rapamune® oral solution; OR
- For sirolimus oral tablets (generic for Rapamune®) - there has been a treatment failure or intolerable side effect with or contraindication to brand Rapamune® oral tablets; OR
- If the request is for a narrow therapeutic index (NTI) drug, such as cyclosporine, every effort should be made to verify if the recipient is currently on a specific brand/generic, then the PA shall be approved for the corresponding product; OR

~~ALL of the following are required:~~

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The prescriber states that the recipient is currently using the requested medication; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

References

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from <https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; Retrieved from <https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

| <u>Revision / Date</u> | <u>Date Implementation Date</u> |
|--|---|
| Single PDL Implementation | May 2019 |
| Separated “Select Therapeutic Classes (Established)” into individual therapeutic class documents / November 2019 | January 2020 November 2019 |
| Added specific wording for use of Rapamune® tablets and oral suspension, formatting changes / April 2021 | April 2021 July 2021 |