Louisiana Medicaid
Immunosuppressives, Oral

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred oral immunosuppressives; **OR**
- Clinical authorization for belumosudil (Rezurock™).

Additional Point-of-Sale edits may apply.

*These agents 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 (Except Rezurock™)

- ~~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**
- 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

Belumosudil (Rezurock™)

Approval Criteria

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient is post-allogeneic hematopoietic cell transplant (HCT), and this is **stated on the request**; **AND**
- The recipient has a diagnosis of chronic graft-versus-host disease (chronic GVHD); **AND**
- The recipient failed treatment with at least **TWO** prior lines of systemic therapy for the treatment of chronic GVHD (e.g., corticosteroids, calcineurin inhibitors, ibrutinib, MMF, methotrexate, rituximab) (**Medication names and dates must be stated on the request**); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a hematologist or oncologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient does not have histologic relapse of underlying cancer or post-transplant lymphoproliferative disease; **AND**
    - Belumosudil will not be used in combination with ibrutinib; **AND**
    - 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.

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 6 months

References

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 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; https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

Rezurock (belumosudil) [package insert]. Warrendale, PA: Kadmon Pharmaceuticals; July 2021. https://rezurockhcp.com/full-prescribing-information.pdf

Saidu NEB, Bonini C, Dickinson A, Grce M, Inngjerdingen M, Koehl U, Toubert A, Zeiser R and Galimberti S (2020) New Approaches for the Treatment of Chronic Graft-Versus-Host Disease: Current Status and Future Directions. Front. Immunol. 11:578314. doi: 10.3389/fimmu.2020.578314

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Separated "Select Therapeutic Classes (Established)" into individual therapeutic class documents / November 2019	January 2020
Added specific wording for use of Rapamune® tablets and oral suspension, formatting changes / April 2021	July 2021
Combined Rezurock™ with current criteria / May 2022	July 2022
Removed wording for use of Rapamune® solution and tablet / October 2023	January 2024