Louisiana Medicaid
Infectious Disorders – Antifungals – Oral Antifungals

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

- Prior authorization for non-preferred oral antifungals; **OR**
- Clinical authorization for ibrexafungerp (Brexafemme®); **OR**
- Clinical authorization for oteseconazole (Vivjoa®™)

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 Non-Preferred Oral Antifungals (Except Brexafemme® and Vivjoa®™)

- 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 request is to *complete a course of treatment that was initiated while the recipient was in an inpatient facility;* 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 authorization approval: 2 weeks to 6 months
An appropriate duration of authorization approval will be determined based upon patient-specific factors and the condition being treated.

Ibrexafungerp (Brexafemme®)

Approval Criteria

- The recipient has a diagnosis of vulvovaginal candidiasis (VVC); **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- If the request is for a non-preferred agent - **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; **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.

OR

- The recipient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC); **AND**
- The prescriber **states on the request** that the recipient has experienced ≥ 3 episodes of vulvovaginal candidiasis in less than one year; **AND**
- The recipient has had a treatment failure, contraindication, or intolerance to a six-month maintenance course of oral fluconazole; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- If the request is for a non-preferred agent - **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 all of 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; **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.

~~If the request is for a non-preferred agent~~
Duration of authorization approval for VVC: 1 week
Duration of authorization approval for RVVC: 6 months

Oteseconazole (Vivjoa®™)

Approval Criteria

- The recipient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC); **AND**
- The prescriber **states on the request** that the recipient has experienced ≥ 3 episodes of vulvovaginal candidiasis in less than one year; **AND**
- The prescriber **states on the request** that the recipient is not of reproductive potential defined by **ONE** of the following:
  - Postmenopausal; **OR**
  - Another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); **AND**
- The recipient has had a treatment failure, contraindication, or intolerance to a six-month maintenance course of oral fluconazole; **AND**
- If the request is for a non-preferred agent - **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 all of 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; **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 authorization approval: 14 weeks

References

Brexafemme (ibrexafungerp) [package insert]. Jersey City, NJ: SCYNEXIS, Inc; November 2022. https://www.brexafemme.com/sites/default/files/2022-11/prescribing-information.pdf

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

Pappas PG, Kauffman CA, Andes DR, et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. CID 2016:62(4):e1-50.

Vivjoa (oteseconazole) [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc; April 2022. https://vivjoa.com/pdf/VIVJOA-Full-Prescribing-Information.pdf

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Separated "Select Anti-Infectives" into individual therapeutic class documents / November 2019	January 2020
Formatting changes / April 2021	July 2021
Combined Vivjoa™ with oral antifungals criteria / November 2022	April 2023
Added clinical criteria for Brexafemme®, updated references / January 2023	July 2023