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|----------------|----------------------------------|----------------|------------------------|--------------------|
| Name:          | Cibinqo (abrocitinib             | )              | Page:                  | 1 of 6             |
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| Applico        | ⊠Illinois                        | □Florida       | □Virginia<br>□Michigan |                    |
| Applies<br>to: | □New Jersey                      | □Maryland      |                        |                    |
| ιο.            | 🗆 Pennsylvania Kids              | 🗆 Florida Kids | □Texas                 |                    |

# Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Cibinqo under the patient's prescription drug benefit.

# **Description:**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

# **FDA-Approved Indication**

Cibinqo is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

All other indications are considered experimental/investigational and not medically necessary.

# **Applicable Drug List:**

Cibingo

#### **Policy/Guideline:**

# **Documentation for all indications:**

The patient is unable to take Dupixent, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

#### **Documentation:**

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:

- 1. Chart notes or medical records showing affected area(s) and affected body surface area (where applicable).
- 2. Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.

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B. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

# **Prescriber Specialties:**

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

# Criteria for Initial Approval:

# **Atopic dermatitis**

- A. Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when the member has experienced an inadequate response or intolerance to at least one biologic or a targeted synthetic drug in the past year.
- B. Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
  - A. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - B. Member meets one of the following:
    - i. Member has had an inadequate treatment response with one of the following in the past year:
      - a) A medium potency to super-high potency topical corticosteroid (see Appendix)
      - b) A topical calcineurin inhibitor
    - ii. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
- C. Member has had an inadequate response to treatment with a systemic drug product (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) indicated for the treatment of atopic dermatitis, or use of these therapies are not advisable for the member.

#### Criteria for Continuation of Therapy: Atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic

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dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

**Note**: For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])\* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

\* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

# **Approval Duration and Quantity Restrictions:**

# **Approval:**

- Initial: 4 months
- **Renewal:** 12 months

# **Quantity Level Limit:**

30 tablets per 30 days

# Appendix:

# Table. Relative potency of select topical corticosteroid products

| Potency              | Drug                                    | Dosage form  | Strength |
|----------------------|---|--|----------|
| I. Super-<br>high    | Augmented betamethasone<br>dipropionate | Ointment, Lotion, Gel  | 0.05%    |
| potency<br>(group 1) | Clobetasol propionate                   | Cream, Gel, Ointment,<br>Solution, Cream (emollient),<br>Lotion, Shampoo, Foam,<br>Spray | 0.05%    |
|                      | Fluocinonide                            | Cream  | 0.1%     |

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| Potency              | Drug                                    | Dosage form                       | Strength              |
|----------------------|---|-----------------------------------|-----------------------|
|                      | Flurandrenolide                         | Таре                              | 4 mcg/cm <sup>2</sup> |
|                      | Halobetasol propionate                  | Cream, Lotion, Ointment,<br>Foam  | 0.05%                 |
| ll. High             | Amcinonide                              | Ointment                          | 0.1%                  |
| potency<br>(group 2) | Augmented betamethasone<br>dipropionate | Cream                             | 0.05%                 |
|                      | Betamethasone dipropionate              | Ointment                          | 0.05%                 |
|                      | Clobetasol propionate                   | Cream                             | 0.025%                |
|                      | Desoximetasone                          | Cream, Ointment, Spray            | 0.25%                 |
|                      |   | Gel                               | 0.05%                 |
|                      | Diflorasone diacetate                   | Ointment, Cream (emollient)       | 0.05%                 |
|                      | Fluocinonide                            | Cream, Ointment, Gel,<br>Solution | 0.05%                 |
|                      | Halcinonide                             | Cream, Ointment                   | 0.1%                  |
|                      | Halobetasol propionate                  | Lotion                            | 0.01%                 |
| Potency              | Drug                                    | Dosage form                       | Strength              |
| III. High            | Amcinonide                              | Cream, Lotion                     | 0.1%                  |
| potency              | Betamethasone dipropionate              | Cream, hydrophilic emollient      | 0.05%                 |
| (group 3)            | Betamethasone valerate                  | Ointment                          | 0.1%                  |
|                      |   | Foam                              | 0.12%                 |
|                      | Desoximetasone                          | Cream, Ointment                   | 0.05%                 |
|                      | Diflorasone diacetate                   | Cream                             | 0.05%                 |
|                      | Fluocinonide                            | Cream, aqueous emollient          | 0.05%                 |
|                      | Fluticasone propionate                  | Ointment                          | 0.005%                |
|                      | Mometasone furoate                      | Ointment                          | 0.1%                  |
|                      | Triamcinolone acetonide                 | Cream, Ointment                   | 0.5%                  |
| IV. Medium           | Betamethasone dipropionate              | Spray                             | 0.05%                 |
| potency              | Clocortolone pivalate                   | Cream                             | 0.1%                  |
| (group 4)            | Fluocinolone acetonide                  | Ointment                          | 0.025%                |
|                      | Flurandrenolide                         | Ointment                          | 0.05%                 |
|                      | Hydrocortisone valerate                 | Ointment                          | 0.2%                  |
|                      | Mometasone furoate                      | Cream, Lotion, Solution           | 0.1%                  |
|                      | Triamcinolone acetonide                 | Cream                             | 0.1%                  |

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| Potency    | Drug                                  | Dosage form                                      | Strength  |  |
|------------|---------------------------------------|--|---|--|
|            |                                       | Ointment   | 0.05% and<br>0.1%                                 |  |
|            |                                       | Aerosol Spray                                    | 0.1%<br>0.2 mg per 2 <sup>.</sup><br>second spray |  |
| V. Lower-  | Betamethasone dipropionate            | Lotion   | 0.05%   |  |
| mid        | Betamethasone valerate                | Cream  | 0.1%  |  |
| potency    | Desonide                              | Ointment, Gel                                    | 0.05%   |  |
| (group 5)  | Fluocinolone acetonide                | Cream  | 0.025%  |  |
|            | Flurandrenolide                       | Cream, Lotion                                    | 0.05%   |  |
|            | Fluticasone propionate                | Cream, Lotion                                    | 0.05%   |  |
|            | Hydrocortisone butyrate               | Cream, Lotion, Ointment,<br>Solution             | 0.1%  |  |
|            | Hydrocortisone probutate              | Cream  | 0.1%  |  |
|            | Hydrocortisone valerate               | Cream  | 0.2%  |  |
|            | Prednicarbate                         | Cream (emollient), Ointment                      | 0.1%  |  |
|            | Triamcinolone acetonide               | Lotion   | 0.1%  |  |
|            |                                       | Ointment   | 0.025%  |  |
| VI. Low    | Alclometasone dipropionate            | Cream, Ointment                                  | 0.05%   |  |
| potency    | Betamethasone valerate                | Lotion   | 0.1%  |  |
| (group 6)  | Desonide                              | Cream, Lotion, Foam                              | 0.05%   |  |
|            | Fluocinolone acetonide                | Cream, Solution, Shampoo, Oil                    | 0.01%   |  |
|            | Triamcinolone acetonide               | Cream, lotion                                    | 0.025%  |  |
|            | Hydrocortisone (base, greater than or | Cream, Ointment, Solution                        | 2.5%  |  |
|            | equal to 2%)                          | Lotion   | 2%  |  |
| VII. Least | Hydrocortisone (base, less than 2%)   | Cream, Ointment, Gel, Lotion,<br>Spray, Solution | 1%  |  |
| potent     |                                       | Cream, Ointment                                  | 0.5%  |  |
| (group 7)  | Hydrocortisone acetate                | Cream  | 2.5%  |  |
|            |                                       | Lotion   | 2%  |  |
|            |                                       | Cream  | 1%  |  |

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; February 2023.

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