



Prior Authorization Criteria

DUPIXENT® (dupilumab) PA Criteria FOR CHRONIC SPONTANEOUS URTICARIA (CSU)

DUPIXENT® (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for the treatment of patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. It is not indicated for other forms of urticaria.

Prior authorization is required for DUPIXENT® (dupilumab) for CSU. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

INITIAL AUTHORIZATION: (will be issued for 6 months)

1. Age of the patient is within the age range as recommended by the FDA label
-AND-
 2. Diagnosis of chronic spontaneous urticaria
-AND-
 3. Patient meets ONE of the following scenarios:
 - a. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1 antihistamines (e.g., cetirizine, loratadine, desloratadine, levocetirizine, diphenhydramine)
-OR-
 - b. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, BOTH of the following taken in combination:
 - i. A second-generation H1 antihistamine (e.g., cetirizine, loratadine, desloratadine, levocetirizine)
-AND-
 - ii. One of the following:
 1. A different second-generation H1 antihistamine
 2. A first-generation H1 antihistamine (e.g., chlorpheniramine, diphenhydramine, hydroxyzine)
 3. An H2 antihistamine (e.g., famotidine, cimetidine, nizatidine)
 4. A leukotriene modifier (e.g., montelukast)
- AND-**
4. Prescribed by or in consultation with an allergist, immunologist, or dermatologist
-AND-

5. Patient is not receiving DUPIXENT® in combination with another biologic medication [e.g., Adbry (tralokinumab-ldrm), Xolair (omalizumab), Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

-AND-

6. Prescribed dose does not exceed an initial dose of 600 mg, followed by 300 mg every other week.

REAUTHORIZATION: (will be issued for 12 months)

1. Positive clinical response to DUPIXENT® therapy (e.g., reduction in exacerbation, itching severity, or hives)

-AND-

2. Patient is not receiving DUPIXENT® in combination with another biologic medication [e.g., Adbry (tralokinumab-ldrm), Xolair (omalizumab), Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

-AND-

3. Prescribed dose does not exceed 300 mg every other week.