Prior authorization checklist

For DUPIXENT® (dupilumab) in moderate-to-severe eosinophilic or OCS-dependent asthma, ages 6+ years

A patient's health plan is likely to require a PA before it approves DUPIXENT as add-on maintenance treatment for appropriate patients with uncontrolled moderate-to-severe asthma. However you choose to submit a PA request (eg, fax, website, phone, CoverMyMeds®[a]), **this checklist can help guide you through the information health plans may need from you.**

[a]CoverMyMeds is a registered trademark of CoverMyMeds, LLC.

INDICATION

DUPIXENT is indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
Limitation of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

DUPIXENT® (dupilumab) Injection
200mg · 300mg

Tips for handling PA requirements from health plans

Please keep in mind that PA requirements are likely to vary, so check with your patient's health plan to ensure you have an accurate list of requirements before you submit

- ☐ Obtain the appropriate PA form after initiating your patient through one of the following:
  - *DUPIXENT MyWay®*
  - CoverMyMeds
  - Insurance provider
  - Specialty pharmacy
- ☐ Fill out all required patient and provider information on the PA form
- ☐ Attach a letter of medical necessity, if required
- ☐ Photocopy the front and back of the patient's pharmacy benefit card
- ☐ Note the payer's reauthorization time frame and requirements
- ☐ Sign all necessary forms. Any and all forms may be rejected if a signature is missing
- ☐ Verify with the health plan to ensure all information and documentation was received and is clear

PA=prior authorization.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Eosinophilic Conditions: Patients being treated for asthma may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis (EGPA), conditions which are often treated with systemic corticosteroid therapy. These events may be associated with the reduction of oral corticosteroid therapy. Healthcare providers should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adult subjects who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult subjects who participated in the asthma development program as well as in adult subjects with co-morbid asthma in the chronic rhinosinusitis with nasal polyposis development program. A causal association between DUPIXENT and these conditions has not been established.

Acute Asthma Symptoms or Deteriorating Disease: Do not use DUPIXENT to treat acute asthma symptoms, acute exacerbations, acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of DUPIXENT.

Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

Tips for handling PA requirements from health plans (cont'd)

Ensure you document the following information according to your patient's diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid-dependent asthma

☐ **Eosinophilic phenotype:**

- Patient's diagnosis, using the appropriate ICD-10-CM code (eg, J45.__)
- Blood eosinophils and last test date
- Results of Asthma Control Test (if available)
- Pre-bronchodilator FEV_1 (<80% in adults or <90% in patients aged 6-17 years)
- Fractional exhaled nitric oxide
- Number of severe exacerbations in the past 12 months defined as:
  - Nonroutine visit
  - Emergency department visit
  - Systemic steroids >3 days
  - Urgent care visit
  - Hospital admission
- Current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy.[a] Examples of requirements include:
  - Inhaled corticosteroids
  - Oral and/or systemic corticosteroids
  - Leukotriene receptor antagonists
  - Biologics
  - Long-acting bronchodilators (long-acting beta-agonists and/or long-acting muscarinic antagonists)

☐ **Oral corticosteroid-dependent asthma:**

- Patient's diagnosis, using the appropriate ICD-10-CM code (eg, J45.__)
- Documentation of steroid dependence (including previously tried and/or failed steroid use and the dose and duration of steroid use)
- Pre-bronchodilator FEV_1 (<80% in adults or <90% in patients aged 6-17 years)
- Fractional exhaled nitric oxide
- Current and prior therapies, documenting the treatment name, dose, duration, and date of each therapy.[a] Examples of requirements include:
  - Inhaled corticosteroids
  - Oral and/or systemic corticosteroids
  - Leukotriene receptor antagonists
  - Biologics
  - Long-acting bronchodilators (long-acting beta-agonists and/or long-acting muscarinic antagonists)

! Please attach chart notes relevant to diagnosis and therapy along with the PA form submission

FEV_1=forced expiratory volume in 1 second; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification.*
[a]Note the payer's reauthorization time frame and requirements.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Arthralgia: Arthralgia has been reported with use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization. Advise patients to report new onset or worsening joint symptoms. If the symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

Parasitic (Helminth) Infections: It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves. Helminth infections (5 cases of enterobiasis and 1 case of ascariasis) were reported in pediatric patients 6 to 11 years old in the pediatric asthma development program.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

DUPIXENT® (dupilumab) Injection
200mg · 300mg

Common reasons for coverage denials

Incomplete information may lead to a denial for DUPIXENT® (dupilumab)

Below are some of the most common causes for denial. It is important that you double check your documentation when you submit your initial PA request to avoid these common causes for denial.

- Clerical error (ie, missing or incorrect ICD-10-CM code)
- Lack of documentation supporting appropriate diagnosis or other required documentation from most recent chart notes
  - Consider indicating on your PA form the page on which the supporting clinical data can be found
- Did not include duration on current therapies or names of all therapies that were tried and failed
- Documentation did not support health plan's criteria for approval of DUPIXENT
- Patient was not treated with prior therapies required by plan
- No reason provided for discontinuation of previous therapy/therapies

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Vaccinations: Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating DUPIXENT. Avoid use of live vaccines in patients treated with DUPIXENT.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1%) in patients with asthma are injection site reactions, oropharyngeal pain, and eosinophilia.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. To enroll or obtain information call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/. Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of DUPIXENT in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

Please see accompanying full Prescribing Information.

For any questions or concerns, or to report side effects with a Sanofi and Regeneron product while enrolled in *DUPIXENT MyWay®*, please contact **1-844-DUPIXEN(T)** (1-844-387-4936) Option 1, Monday–Friday, 8 AM–9 PM Eastern time.

sanofi | REGENERON®

DUPIXENT® (dupilumab) Injection
200mg · 300mg