Dupixent® (dupilumab) for COPD – New indication approval

- On September 27, 2024, Regeneron and Sanofi announced the approval of a new indication for Dupixent® (dupilumab) for chronic obstructive pulmonary disease COPD). Dupixent is now approved as add-on maintenance treatment in adults with uncontrolled COPD and an eosinophilic phenotype.
    - Dupixent is the first biologic approved for the treatment of COPD.
    - Other existing indications for Dupixent include atopic dermatitis, asthma (ages 6 years and above), chronic sinusitis with nasal polyps, eosinophilic esophagitis, and prurigo nodularis.
- COPD is respiratory disease that damages the lungs and causes progressive lung function decline. Symptoms include persistent cough, excessive mucus production and shortness of breath that may impair the ability to perform routine daily activities. A subset of COPD patients, the eosinophilic phenotype, have high levels of white blood cells (eosinophils) and are more likely to experience exacerbations and COPD-related hospitalizations.
    - COPD affects approximately 16 million adults in the US.
    - The current standard of care includes inhaled beta agonists, inhaled muscarinic antagonists, and inhaled corticosteroids, usually in combination.
    - Half of COPD patients experience exacerbations despite triple inhaled therapy.
    - Per the manufacturer, approximately 300,000 people live with inadequately controlled COPD and the eosinophilic phenotype.
- The safety and efficacy of Dupixent as add-on maintenance treatment of adult patients with inadequately controlled COPD and an eosinophilic phenotype was evaluated in two randomized, double-blind, multicenter, parallel-group, placebo-controlled trials: BOREAS and NOTUS. Both trials enrolled individuals with moderate to severe COPD and minimum blood eosinophil count of 300 cell/mcL at baseline.
    - Subjects were randomized to receive DUPIXENT 300 mg subcutaneously every two weeks or placebo in addition to their background maintenance therapy for 52 weeks.
    - The primary endpoint was annualized rate of moderate to severe COPD exacerbations during the 52-week treatment period.
        - In the BOREAS trial Dupixent-treated patients experienced 0.78 exacerbations/year vs 1.10 exacerbations/year with placebo; Rate ratio vs placebo 0.71 (95% CI 0.58 – 0.86); approximately 30% reduction
        - In the NOTUS trial Dupixent-treated patients experienced 0.86 exacerbations/year vs 1.30 exacerbations/year with placebo; Rate ratio vs placebo 0.66 (95% CI 0.5 – 0.82); approximately 34% reduction
- The recommended dose of Dupixent for COPD is 300 mg given as a subcutaneous injection every other week.

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- Refer to the Dupixent drug label for dosing for other indications