SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Dupixent® (dupilumab)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Diagnosis	Recommended Dose
Atopic Dermatitis	**Adult:** • **Initial:** 600 mg (given as two 300 mg injections) • **Maintenance:** 300 mg once every other week **Children ≥ 6 years and Adolescents ≤ 17 years:** • **15 to < 30 kg – Initial: 600** mg once (administered as two 300 mg injections). **Maintenance:** 300 mg every 4 weeks • **30 to < 60 kg – Initial:** 400 mg once (administered as two 200 mg injections). **Maintenance:** 200 mg every other week • **60 kg – Initial:** 600 mg once (administered as two 300 mg injections). **Maintenance:** 300 mg every other week **Children ≥ 6 months to 5 years of age:** • **5 to <15 kg – Initial and maintenance:** 200mg (one 200 mg injection) every 4 weeks • **15 to < 30 kg – Initial and maintenance:** 300mg (one 300 mg injection) every 4 weeks

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Diagnosis	Recommended Dose
Asthma, moderate to severe	**Children ≥ 12 years, Adolescents and Adults:** • **Initial:** 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg injections) • **Maintenance:** 200 mg (following 400 mg initial dose) or 300 mg (following 600 mg initial dose) once every other week **Children ≥ 6 years and Adolescents < 12 years:** • **15 to <30 kg**: 100 mg every other week or 300 mg every 4 weeks. • **≥ 30 kg:** 200 mg every other week
Asthma, oral corticosteroid dependent or with comorbid moderate to severe atopic dermatitis	• **Initial:** 600 mg (given as two 300 mg injections) • **Maintenance:** 300 mg once every other week
Chronic Obstructive Pulmonary Disease (COPD)	• 300 mg once every other week
Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)	• 300 mg once every other week • 200 mg syringes are **NOT** approved for chronic rhinosinusitis with nasal polyposis
Chronic Spontaneous Urticaria (CSU)	**Adults:** • **Initial:** 600 mg (given as two 300 mg injections) • **Maintenance:** 300 mg once every other week **Children ≥ 12 years to 17 years of age:** • 30 to less than 60 kg: o **Initial:** 400 mg (given as two 200 mg injections) o **Maintenance:** 200 mg once every other week • 60 kg or more: o **Initial:** 600 mg (given as two 300 mg injections) o **Maintenance:** 300 mg once every other week
Eosinophilic Esophagitis (EoE)	**Children ≥ 1 year, Adolescents and Adults:** • **15 to <30 kg: Initial and maintenance:** 200 mg once every other week • **30 to <40 kg: Initial and maintenance:** 300 mg once every other week • **40 kg or more:** 300 mg once every week
Prurigo Nodularis (PN)	• **Initial:** 600 mg (given as two 300 mg injections) • **Maintenance:** 300 mg once every other week

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Quantity Limits:

- 100 mg/0.67 mL prefilled syringe: 2 prefilled syringes per 28 days
- 200 mg/1.14 mL pen-injector: 2 pens per 28 days
- 200 mg/1.14 mL prefilled syringe: 2 prefilled syringes per 28 days
- 300 mg/2 mL pen-injector: 2 pens per 28 days
- 300 mg/2 mL prefilled syringe: 2 prefilled syringes per 28 days

***The Health Plan considers the use of concomitant therapy with Adbry™, Cinqair®, Dupixent®, Fasenra®, Nucala®, Tezspire™ and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Adbry™, Cinqair®, Fasenra®, Nucala®, Tezspire™ or Xolair® authorization on file, all subsequent requests for Dupixent® will NOT be approved.**

- Will the member be discontinuing a previously prescribed biologic if approved for requested medication?

  ❑ Yes **OR** ❑ No

- If yes, please list the medication that will be discontinued and the medication that will be initiated upon approval along with the corresponding effective date.

  Medication to be discontinued: _____ **Effective date:** _____

  Medication to be initiated: _____ **Effective date:** _____

CLINICAL CRITERIA: Check below all that apply. **All criteria must be met for approval**. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ Diagnosis: Moderate-to-Severe Atopic Dermatitis

Initial Authorization: 4 months

- ❑ Prescribed by or in consultation with an allergist, dermatologist or immunologist
- ❑ Member is 6 months of age or older
- ❑ Member has a diagnosis of **moderate to severe atopic dermatitis** with disease severity confirmed by **ONE** of the following:
  - ❑ Body Surface Area (BSA) involvement >10%
  - ❑ Eczema Area and Severity Index (EASI) score ≥ 16
  - ❑ Investigator's Global Assessment (IGA) score ≥ 3
  - ❑ Scoring Atopic Dermatitis (SCORAD) score ≥ 25

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- ❑ Member has tried and failed at least **TWO** of the following therapies **(check all that apply; verified by chart notes and/or pharmacy paid claims)**:
  - ❑ 30 days (14 days for very high potency) of therapy with **ONE** medium to very-high potency topical corticosteroid in the past 180 days
  - ❑ 30 days of therapy with **ONE** topical calcineurin inhibitor in the past 180 days (e.g., tacrolimus ointment, pimecrolimus cream*) (***requires prior authorization**)
  - ❑ 30 days of therapy with **ONE** topical phosphodiesterase-4 enzyme inhibitor in the past 180 days (e.g., Eucrisa*, Zoryve 0.15% cream*) **(*requires prior authorization)**
  - ❑ 30 days of therapy with **ONE** topical janus kinase inhibitor in the past 180 days (e.g., Opzelura*) **(*requires prior authorization)**
  - ❑ 90 days of therapy with **ONE** generic oral DMARD (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)

❑ Diagnosis: Moderate-to-Severe Atopic Dermatitis

Reauthorization: 12 months

- ❑ Member has experienced a positive clinical response to Dupixent® therapy (e.g., reduced BSA involvement, decrease in severity based on physician assessment)

❑ Diagnosis: Moderate-to-Severe Asthma

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an allergist, immunologist or pulmonologist
- ❑ Member is 6 years of age or older
- ❑ Member has been diagnosed with **ONE** of the following (check the diagnoses below that applies):
  - ❑ **1.) Eosinophilic phenotype asthma** – defined by a baseline (pre-Dupixent® treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter and meets **ALL** the following clinical criteria:
    - ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy **for at least 90 consecutive days** within a year of request **(verified by pharmacy paid claims)**:
      - ❑ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
      - ❑ One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol))

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- ❑ Member has experienced at least **ONE** of the following **(check all that apply)**:
  - ❑ **ONE (1)** or more exacerbations requiring additional medical treatment (e.g., oral corticosteroids, emergency department, urgent care visits or hospitalizations within the past 12 months)
  - ❑ Any prior intubation for an asthma exacerbation
- ❑ Member has a baseline forced expiratory volume (FEV1) < 80% predicted normal (< 90% for members 6-17 years old) submitted within year of request
- ❑ Provider must submit member blood eosinophil count after a trial and failure of at least 90 days of therapy with high dose inhaled corticosteroids **AND** long-acting inhaled beta-2 agonist. A failure of these medications is defined as a blood count > 150 cells/microliter **(submit labs collected within the past 12 months)**

  Eosinophil count: _____ **Date:** _____

❑ **2.) Oral corticosteroid dependent asthma** and meets **ALL** the following clinical criteria:

- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy **for at least 90 consecutive days** within a year of request **(verified by pharmacy paid claims)**:
  - ❑ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
  - ❑ One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol))
- ❑ Member has experienced at least **ONE** of the following **(check all that apply)**:
  - ❑ **ONE (1)** or more exacerbations requiring additional medical treatment (e.g., oral corticosteroids, emergency department, urgent care visits or hospitalizations within the past 12 months)
  - ❑ Any prior intubation for an asthma exacerbation
- ❑ Member has a baseline forced expiratory volume (FEV1) < 80% predicted normal (< 90% for members 6-17 years old) submitted within year of request

❑ Diagnosis: Moderate-to-Severe Asthma

Reauthorization: 12 months

- ❑ Member has experienced a sustained positive clinical response to Dupixent® therapy as demonstrated by at least **ONE** of the following **(check all that apply)**:
  - ❑ Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
  - ❑ Reduction in the dose of inhaled corticosteroids required to control asthma
  - ❑ Reduction in the use of oral corticosteroids to treat/prevent exacerbation
  - ❑ Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath or nocturnal awakenings

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- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications **(verified by pharmacy paid claims)**:
  - ❑ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
  - ❑ One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol))

❑ Diagnosis: Chronic Obstructive Pulmonary Disease (COPD)

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a pulmonologist
- ❑ Member is 18 years of age or older
- ❑ Member has a diagnosis of moderate to severe Chronic Obstructive Pulmonary Disease (COPD) confirmed with spirometry demonstrating **ONE** of the following:
  - ❑ FEV1/FVC ratio <0.7 post-bronchodilation
  - ❑ Post-bronchodilator FEV1 % predicted of ≥ 30% and ≤ 80%
- ❑ Member is symptomatic confirmed by **ONE** of the clinical assessments:
  - ❑ Modified Medical Research Council (mMRC) dyspnea grade ≥ 2 (range 0-4)
  - ❑ COPD Assessment Test (CAT) score ≥ 10 (range 0-40)
- ❑ Member has experienced **ONE** of the following **(chart notes must be submitted)**:
  - ❑ At least two (2) exacerbations treated with short-acting bronchodilators and oral corticosteroids, with or without antibiotics in the past 12 months
  - ❑ At least one (1) exacerbation requiring hospitalization in the past 12 months
- ❑ Member has experienced signs or symptoms of chronic bronchitis (e.g., chronic productive cough) for ≥ 3 months in the previous 12 months **(chart notes must be submitted)**
- ❑ Provider must submit a member blood eosinophil count level greater than or equal to 300 cells per microliter following at least 90 days of therapy of dual or triple-maintenance therapies **(submit labs collected within the past 12 months)**
- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy **for at least 90 consecutive days** within year of the request **(verified by chart notes and/or pharmacy paid claims)**:
  - ❑ Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®), long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®) alone if inhaled corticosteroid (ICS) is contraindicated **(must submit documentation that an ICS is contraindicated)**
- ❑ Member is requesting Dupixent® (dupilumab) as add-on maintenance therapy to dual or triple therapy **(verified by chart notes and/or pharmacy paid claims)**

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❑ Diagnosis: Chronic Obstructive Pulmonary Disease (COPD)

Reauthorization: 12 months

- ❑ Member has experienced a sustained positive clinical response to Dupixent® therapy as demonstrated by at least **ONE** of the following **(check all that apply; chart notes must be submitted)**:
  - ❑ Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
  - ❑ Reduction in exacerbations (e.g., decrease oral corticosteroids) or fewer hospitalizations
  - ❑ Reduction in dyspnea symptoms such as chest tightness, shortness of breath
- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications **(verified by chart notes and/or pharmacy paid claims)**:
  - ❑ Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®), long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®) alone if inhaled corticosteroid (ICS) is contraindicated **(must submit documentation that an ICS is contraindicated)**
- ❑ Member continues to use Dupixent® (dupilumab) as add-on maintenance therapy to dual or triple therapy **(verified by chart notes and/or pharmacy paid claims)**

❑ Diagnosis: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an allergist, immunologist or otolaryngologist
- ❑ Member is 12 years of age or older
- ❑ Member has a **diagnosis of CRSwNP** confirmed by the American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline (Update): Adult Sinusitis (AAO-HNSF 2015)/American Academy of Allergy Asthma & Immunology (AAAAI) with **ONE** of the following clinical procedures:
  - ❑ Anterior rhinoscopy
  - ❑ Nasal endoscopy
  - ❑ Computed tomography (CT)
- ❑ Member has a documented diagnosis of chronic rhinosinusitis defined by at least 12 weeks of the following:
  - ❑ Mucosal inflammation **AND** at least **TWO** of the following:
    - ❑ Decreased sense of smell
    - ❑ Facial pressure, pain, fullness
    - ❑ Mucopurulent drainage
    - ❑ Nasal obstruction

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- ❑ Member has tried and failed intranasal corticosteroids **for at least 30 consecutive days** within a year of request **(verified by pharmacy paid claims)**
- ❑ Member is refractory, ineligible or intolerant to **ONE** of the following:
  - ❑ Systemic corticosteroids
  - ❑ Sino-nasal surgery
- ❑ Member is requesting Dupixent® (dupilumab) as add-on therapy to maintenance intranasal corticosteroids **(verified by pharmacy paid claims)**

❑ Diagnosis: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Reauthorization: 12 months

- ❑ Member has experienced a positive clinical response to Dupixent® therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell, reduction in use of oral corticosteroids)
- ❑ Member has been compliant with Dupixent® therapy and continues to receive therapy with an intranasal corticosteroid **(verified by pharmacy paid claims)**

❑ Diagnosis: Chronic Spontaneous Urticaria (CSU)

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an allergist, dermatologist, or pulmonologist
- ❑ Member is ≥ 12 years of age
- ❑ Member has had a confirmed diagnosis of chronic spontaneous urticaria for at least 6 weeks with or without angioedema
- ❑ Member has failed **ONE (1)** of the following H1 antihistamines at 4 times the initial dose for at least 4 weeks:

❑ levocetirizine 10 mg – 20 mg QD	❑ desloratadine 10 – 20 mg QD	❑ fexofenadine 120 mg – 240 mg BID
❑ cetirizine 20 mg – 40 mg QD	❑ loratadine 20 mg – 40 mg QD	

- ❑ Member has remained symptomatic despite treatment with **ALL** the following therapies **(verified by pharmacy paid claims)**:
  - ❑ Hydroxyzine 10 mg – 25 mg taken daily
  - ❑ Leukotriene Antagonist for at least 4 weeks (e.g., montelukast, zafirlukast)
  - ❑ H2 antihistamine, for treatment of acute exacerbations, for at least 5 days (e.g., famotidine, cimetidine)

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❑ Diagnosis: Chronic Spontaneous Urticaria (CSU)

Reauthorization: 12 months

- ❑ Members disease status has been re-evaluated since the last authorization to confirm the members condition warrants continued treatment **(chart notes must be submitted for documentation)**
- ❑ Provider has submitted chart notes documenting the members symptoms have improved (e.g., a decrease in the number of hives, a decrease in the size of hives, and improvement of itching)

❑ Diagnosis: Eosinophilic Esophagitis (EoE)

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an allergist, immunologist, pulmonologist or gastroenterologist
- ❑ Member is 1 year of age or older and weighs at least 15 kg
- ❑ Member has a documented diagnosis of EoE as evidenced by at least 15 intraepithelial eosinophils per high-powered microscopy field (eos/hpf), or 60 eosinophils/mm^2 on endoscopic biopsy **(chart notes must be submitted)**
- ❑ Member has a history of an average of at least two (2) episodes of dysphagia, with intake of solids, per week or prior history of esophageal dilation
- ❑ Provider attests to **ONE** of the following:
  - ❑ Member does **NOT** have a diagnosis of gastroesophageal reflux disease (GERD) and/or GERD diagnosis has been ruled out
  - ❑ Member has a diagnosis of GERD that is being adequately managed by high dose PPI therapy (e.g., omeprazole 40-80 mg daily)
- ❑ Provider attestation to other causes of esophageal eosinophilia have been ruled out (i.e., active helicobacter pylori infection, hypereosinophilic syndrome and eosinophilic granulomatosis with polyangiitis, Crohn's disease, ulcerative colitis, celiac disease, achalasia)
- ❑ Member meets **ONE** of the following:
  - ❑ Member has tried an elemental diet or an empiric, 6-food elimination diet (i.e., dairy, eggs, wheat, soy, peanuts, fish/shellfish) to treat/manage eosinophilic esophagitis
  - ❑ Provider has determined that the individual is **NOT** an appropriate candidate for dietary modifications **(clinical rationale must be documented in submitted chart notes)**
- ❑ Member meets **ONE** of the following:
  - ❑ Member has tried and failed swallowed topical glucocorticoids (e.g., nebulized or swallowed nasal drops such as budesonide nasal spray or nebulizer solution) for at least 6 -12 weeks
  - ❑ Provider has determined that the individual is **NOT** an appropriate candidate for prerequisite use of swallowed topical glucocorticoids due to the member's age

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❑ Diagnosis: Eosinophilic Esophagitis (EoE)

Reauthorization: 12 months

- ❑ Member has experienced disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: dysphagia/swallowing pain, including chest pain, stomach pain, heartburn, regurgitation, and vomiting **(chart notes must be submitted)**
- ❑ Member is in histologic remission defined as a peak esophageal intraepithelial eosinophil count of ≤ 6 eos/hpf

❑ Diagnosis: Prurigo Nodularis (PN)

Initial Authorization: 6 months

- ❑ Prescribed by or in consultation with an allergist, dermatologist or immunologist
- ❑ Member is 18 years of age or older
- ❑ Member has a diagnosis of prurigo nodularis (PN) for at least three (3) months **(chart notes must be submitted)**
- ❑ Member's disease is **NOT** secondary to medications or medical conditions (i.e., neuropathy or psychiatric disease)
- ❑ Member has an average worst itch score of at least 7 or greater on the Worst Itch Numeric Rating Scale (WI-NRS 0-10) **(chart notes must be submitted)**
- ❑ Member has at least 20 prurigo nodularis lesions, in total, on legs, arms and/or trunk **(chart notes must be submitted)**
- ❑ Member has tried and failed, has a contraindication, or intolerance to **ALL** four of the following therapies **(chart notes documenting contraindication(s) or intolerance must be attached; trials will be verified using pharmacy claims and/or submitted chart notes)**:
  - ❑ 30 days (14 days for very high potency) of therapy with **ONE** medium to very-high potency topical corticosteroid in the past 180 days
  - ❑ 30 days of therapy with **ONE** of the following topical calcineurin inhibitors in the past 180 days:
    - ❑ tacrolimus 0.03 % or 0.1% ointment
    - ❑ pimecrolimus 1% cream (generic Elidel) **[requires prior authorization]**
  - ❑ 90 days of phototherapy (e.g., NB UV-B, PUVA) unless the member is not a candidate and/or has an intolerance or contraindication to therapy
  - ❑ 90 days of therapy with **ONE** of the following oral immunosuppressants in the past 180 days:
    - ❑ azathioprine
    - ❑ cyclosporine
    - ❑ methotrexate

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❑ **Diagnosis: Prurigo Nodularis (PN)**
Reauthorization: 12 months

- ❑ Member has experienced disease response as indicated by improvement (reduction) in signs and symptoms compared to baseline in one or more of the following: pruritus severity, number of lesions, and/or WINRS **(chart notes must be submitted)**

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.**