IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 6, 2026. At this meeting, Commission members reviewed and discussed prior authorization (PA) criteria for Apolipoprotein C-III (ApoC-III) Inhibitors; Biologicals for Hidradenitis Suppurativa; Dupilumab (Dupixent); and Idiopathic Pulmonary Fibrosis and Related Lung Diseases. The following recommendations have been made by the DUR Commission:

Apolipoprotein C-III (ApoC-III) Inhibitors
(formerly Olezarsen [Tryngolza])

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for olezarsen (Tryngolza). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic testing, (e.g., biallelic pathogenic variants in FCS-causing genes [*LPL, GPIHBP1, APOA5, APOC2, or LMF1*]) (attach genetic testing results); and
3. The patient has a current fasting triglyceride level of 880 mg/dL or greater (attach current lipid panel obtained within the past 30 days); and
4. The patient will use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and
5. Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.

If the criteria for coverage are met, initial requests will be given for 6 months. Requests for continuation of therapy will be considered at 12-month intervals under the following conditions:

1. Documentation of a decrease in fasting triglyceride level from baseline (attach current lipid panel obtained within the past 30 days); and
2. Patient continues to use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and
3. Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for *apoC-III inhibitors* ~~olezarsen (Tryngolza)~~. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic testing, (e.g., biallelic pathogenic variants in FCS-causing genes [*LPL, GPIHBP1, APOA5, APOC2, or LMF1*]) (attach genetic testing results); and
3. The patient has a current fasting triglyceride level of 880 mg/dL or greater (attach current lipid panel obtained within the past 30 days); and
4. The patient will use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and
5. *Medication will not be used concomitantly with other apoC-III inhibitors; and*
6. Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.

If the criteria for coverage are met, initial requests will be given for ~~6~~ *12* months. Requests for continuation of therapy will be considered at 12-month intervals under the following conditions:

1. Documentation of a decrease in fasting triglyceride level from baseline (attach current lipid panel obtained within the past 30 days); and
2. Patient continues to use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and
3. Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.

Biologicals for Hidradenitis Suppurativa

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for biologicals FDA approved or compendia indicated for the treatment of Hidradenitis Suppurativa (HS). Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and

therapy failure with a preferred biologic agent. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
3. Patient has at least three (3) abscesses or inflammatory nodules; and
4. Patient has documentation of adequate trials and therapy failures with the following:
    a. Daily treatment with topical clindamycin;
    b. Oral clindamycin plus rifampin;
    c. Maintenance therapy with a preferred tetracycline.

If criteria for coverage are met, initial requests will be given for 4 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for biologicals FDA approved or compendia indicated for the treatment of Hidradenitis Suppurativa (HS). Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
~~3. Patient has at least three (3) abscesses or inflammatory nodules; and~~
4. Patient has documentation of *an* adequate trial~~s~~ and therapy failure~~s~~ with *at least one oral antibiotic/oral antibiotic combination (e.g., doxycycline, clindamycin, rifampin).* ~~the following:~~
    ~~a. Daily treatment with topical clindamycin;~~
    ~~b. Oral clindamycin plus rifampin;~~
    ~~c. Maintenance therapy with a preferred tetracycline~~.

If criteria for coverage are met, initial requests will be given for 4 months. Additional authorizations will be considered upon documentation of ~~clinical~~ *a positive* response to therapy. ~~Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.~~

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Dupilumab (Dupixent)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Patient has failed to respond to good skin care and regular use of emollients; and
    b. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    c. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    d. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) or with oral corticosteroid dependent asthma; and
    a. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and
    b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long-acting beta $_2$ agonist [LABA], or leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    c. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. One (1) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; or
5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or
6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and

a. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
b. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
c. Documentation of previous trials and therapy failures with all of the following:
    i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
    ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension): and
    iii. Dietary therapy; or

7. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    b. Patient has ≥ 20 nodular lesions (attach documentation); and
    c. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; or
8. Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; and
    a. Patient has moderate to severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:
        i. FEV1/FVC ratio < 0.7, and
        ii. FEV1 % predicted between 30% to 79%; and
    b. Patient has a minimum blood eosinophil count of 300 cells/mcL, measured within the past 12 months; and
    c. Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to:
        i. Triple therapy with all of the following treatments:
            1. Long-acting muscarinic antagonist/anticholinergic (LAMA); and
            2. Long-acting beta-2 agonist (LABA); and
            3. Inhaled corticosteroid (ICS); or
        ii. Double therapy with both of the following if ICS is contraindicated
            1. LABA; and
            2. LAMA; and
    d. Patient has history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy (defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and
    e. Patient will continue to receive maintenance therapy (as documented above) concomitantly with dupilumab; or
9. Patient has a diagnosis of chronic spontaneous urticaria (CSU) with no known cause; and
    a. Patient has documentation of an adequate trial and therapy failure with a preferred second generation H1 receptor antihistamine for at least 2 weeks; or
10. Patient has a diagnosis of bullous pemphigoid (BP); and
    a. Is initiated with a tapering course of oral corticosteroids.

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD, CSU, and BP which will receive an initial authorization

of 12 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and continued use of add-on maintenance therapy, where indicated.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted, and/or stricken)
Prior authorization (PA) is required for Dupixent (dupilumab). Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Patient has failed to respond to good skin care and regular use of emollients; and
    b. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    c. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    d. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) or with oral corticosteroid dependent asthma; and
    a. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and
    b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long-acting beta $_2$ agonist [LABA], or leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    c. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. One (1) or more exacerbations in the previous year or
        ii. Require daily oral corticosteroids for at least 3 days; or
5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or

6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and
    a. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
    b. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
    c. Documentation of previous trials and therapy failures with all of the following:
        i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
        ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension): and
        iii. Dietary therapy; or
7. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    b. Patient has ≥ 20 nodular lesions (attach documentation); and
    c. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; or
8. Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; and
    a. Patient has moderate to severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:
        i. FEV1/FVC ratio < 0.7, and
        ii. FEV1 % predicted between 30% to 79%; and
    b. Patient has a minimum blood eosinophil count of 300 cells/mcL, measured within the past 12 months; and
    c. Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to:
        i. Triple therapy with all of the following treatments:
            1. Long-acting muscarinic antagonist/anticholinergic (LAMA); and
            2. Long-acting beta agonist (LABA); and
            3. Inhaled corticosteroid (ICS); or
        ii. Double therapy with both of the following if ICS is contraindicated
            1. LABA; and
            2. LAMA; and
    d. Patient has history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy (defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and
    e. Patient will continue to receive maintenance therapy (as documented above) concomitantly with dupilumab; or
9. Patient has a diagnosis of chronic spontaneous urticaria (CSU) with no known cause; and
    a. Patient has documentation of an adequate trial and therapy failure with a preferred second generation H1 receptor antihistamine for at least 2 weeks; or
10. Patient has a diagnosis of bullous pemphigoid (BP); and
    a. Is initiated with a tapering course of oral corticosteroids*; or*
11. *Patient has a diagnosis of allergic fungal rhinosinusitis (AFRS); and*
    a. *Patient has a history of sino-nasal surgery*.

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD, CSU, ~~and~~ BP*, and AFRS* which will receive an initial authorization of 12 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and continued use of add-on maintenance therapy, where indicated.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Idiopathic Pulmonary Fibrosis and Related Lung Diseases
(formerly Pirfenidone [Esbriet]/Nintedanib [Ofev])

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient meets the FDA approved age; and
2. Is prescribed by a pulmonologist; and
3. Patient does not have hepatic impairment as defined below:
    a. Nintedanib – Patient does not have moderate or severe hepatic impairment (Child Pugh B or C); or
    b. Pirfenidone – Patient does not have severe hepatic impairment (Child Pugh C); and
4. Patient does not have renal impairment as defined below:
    a. Nintedanib – Patient does not have severe renal impairment (CrCl <30 ml/min) or end-stage renal disease; or
    b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
5. Patient does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib; and
6. Patient has a diagnosis of idiopathic pulmonary fibrosis (nintedanib or pirfenidone) as confirmed by one of the following (attach documentation):
    a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
    b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
    c. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational exposures, connective tissue disease, and drug toxicity; and
    d. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
    e. Patient has a carbon monoxide diffusion capacity (%Dlco) of ≥30% predicted; or
7. Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib) as confirmed by the following (attach documentation):

a. Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and
b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and
c. Patient has a carbon monoxide diffusion capacity (%Dlco) of ≥ 30-89% predicted; or

8. Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) and confirmed by the following (attach documentation):
    a. Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and
    b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and
    c. Patient has a carbon monoxide diffusion capacity (%Dlco) of ≥ 30-79% predicted; and
    d. Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:
        i. A relative decline in the FVC of at least 10% predicted; or
        ii. A relative decline in the FVC of 5-9% predicted combined with at least one of the following:
            1. Worsening respiratory symptoms; or
            2. Increased extent of fibrosis on HRCT; or
        iii. Worsening respiratory symptoms and an increased extent of fibrotic changes on HRCT only.

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6-month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet) or nintedanib (Ofev) is confirmed; and
2. Documentation of a positive response to therapy, defined as meeting at least one of the following:
    a. Rate of lung function decline slowed; or
    b. Improved or no worsening of symptoms of cough, shortness of breath; and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted, and/or stricken)
Prior authorization (PA) is required for *medications used to treat idiopathic pulmonary fibrosis and related lung diseases.* ~~pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered.~~ *Payment for non-preferred agents will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent that is FDA approved or compendia indicated for the submitted diagnosis, when applicable.* Payment will be considered for patients when the following criteria are met:

1. *Request adheres to all FDA approved labeling including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations* ~~Patient meets the FDA approved age~~; and
2. Is prescribed by a pulmonologist; and
3. ~~Patient does not have hepatic impairment as defined below:~~

a. ~~Nintedanib – Patient does not have moderate or severe hepatic impairment (Child Pugh B or C); or~~
b. ~~Pirfenidone – Patient does not have severe hepatic impairment (Child Pugh C); and~~

4. ~~Patient does not have renal impairment as defined below:~~
   a. ~~Nintedanib – Patient does not have severe renal impairment (CrCl <30 ml/min) or end-stage renal disease; or~~
   b. ~~Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and~~
5. Patient does not utilize non-prescribed inhalants, ~~such as~~ *including but not limited to* vaping or other inhaled ~~tobacco~~ products, prior to initiating therapy and has been instructed to avoid ~~tobacco~~ *these* products while using *requested medication(s)* ~~pirfenidone or nintedanib~~; and
6. Concomitant use of nintedanib and pirfenidone will not be considered; and
7. Documentation of an inadequate response to monotherapy with nintedanib or pirfenidone, at up to maximally indicated doses, is required prior to combination therapy with nerandomilast; and
8. Patient has a diagnosis of idiopathic pulmonary fibrosis (*nerandomilast,* nintedanib*,* or pirfenidone) as confirmed by one of the following (attach documentation):
   a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
   b. A surgical lung biopsy demonstrating ~~usual interstitial pneumonia (~~UIP~~)~~; and
   c. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational exposures, connective tissue disease, and drug toxicity; and
   d. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC):
      i. ≥ 50% predicted *for nintedanib or pirfenidone*; *or*
      ii. *≥ 45% predicted for nerandomilast;* and
   e. Patient has a carbon monoxide diffusion capacity (%Dlco):
   f. ~~of~~ ≥ 30% predicted *for nintedanib or pirfenidone; and*
   g. *≥ 25% predicted for nerandomilast; or*
9. Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib) as confirmed by the following (attach documentation):
   a. Documentation of a ~~chest high resolution computed tomography (~~HRCT~~)~~ scan showing fibrosis affecting ≥ 10% of the lungs; and
   b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and
   c. Patient has a ~~carbon monoxide diffusion capacity (~~%Dlco~~)~~ of ≥ 30-89% predicted; or
10. Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (*progressive pulmonary fibrosis [PPF])* (nintedanib *or nerandomilast*) and confirmed by the following (attach documentation):
    a. Documentation of a ~~chest high resolution computed tomography (~~HRCT~~)~~ scan showing fibrosis affecting ≥ 10% of the lungs; and

b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and
c. Patient has a ~~carbon monoxide diffusion capacity (~~%DIco~~)~~ of*:*
    i. ≥ 30-79% predicted *for nintedanib*; *or*
    ii. *≥ 25% predicted for nerandomilast;* and
d. Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months ~~despite standard treatment with an agent other than nintedanib or pirfenidone~~:
    i. A relative decline in the FVC of at least 10% predicted; or
    ii. A relative decline in the FVC of 5-9% predicted combined with at least one of the following:
        1. Worsening respiratory symptoms; or
        2. Increased extent of fibrosis on HRCT; or
    iii. Worsening respiratory symptoms and an increased extent of fibrotic changes on HRCT only.

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6-month intervals when the following criteria are met:

1. Adherence to *medication* ~~pirfenidone (Esbriet) or nintedanib (Ofev)~~ is confirmed; and
2. Documentation of a positive response to therapy, defined as meeting at least one of the following:
    a. Rate of lung function decline slowed; or
    b. Improved or no worsening of symptoms of cough, shortness of breath; and
3. Documentation is provided that the patient has remained ~~tobacco-~~free *from use of non-prescribed inhalants, including but not limited to vaping and other inhaled products*.~~; and~~
4. ~~ALT, AST, and bilirubin are assessed periodically during therapy.~~

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations regarding Apolipoprotein C-III (ApoC-III) Inhibitors; Biologicals for Hidradenitis Suppurativa; Dupilumab (Dupixent); and Idiopathic Pulmonary Fibrosis and Related Lung Diseases.

Sincerely,

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid

Cc: Erin Halverson, R.Ph, Iowa Medicaid
Gina Kuebler, R.Ph, Iowa Medicaid