IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 1, 2024. At this meeting, the DUR Commission members discussed updated prior authorization (PA) criteria for Biologicals for Arthritis; Biologicals for Hidradenitis Suppurativa; Dupilumab (Dupixent); Select Preventative Migraine Treatments; and Hepatitis C Treatment, Direct Acting Antivirals, as well as the removal of PA criteria for Febuxostat (Uloric). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a February 9, 2024 letter that was sent to them detailing the updated PA criteria for Biologicals for Arthritis; Biologicals for Hidradenitis Suppurativa; Dupilumab (Dupixent); Select Preventative Migraine Treatments; Hepatitis C Treatment, Direct Acting Antivirals, and removal of PA criteria for Febuxostat (Uloric).

Biologicals for Arthritis

Current Clinical Prior Authorization

Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling, including age, indication, dosing, and contraindications. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and
2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
3. Patient has a diagnosis of rheumatoid arthritis (RA); with
    a. Documentation of a trial and inadequate response, at a maximally tolerated

dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated); or

4. Patient has a diagnosis of moderate to severe psoriatic arthritis; with
    a. Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
5. Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis; with
    a. Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

In addition to the above:
Requests for TNF Inhibitors:

1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and
2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.

Requests for Interleukins:

1. Medication will not be given concurrently with live vaccines.

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 (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling *for requested drug and indication*, including age, ~~indication,~~ dosing, ~~and~~ contraindications*, warnings & precautions, drug interactions, and use in specific populations*. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

~~1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and~~
~~2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and~~
3. Patient has a diagnosis of rheumatoid arthritis (RA); with
    a. Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (hydroxycholoroquine, sulfasalazine, or leflunomide may be used if methotrexate is contraindicated); or
4. Patient has a diagnosis of moderate to severe psoriatic arthritis; with
    a. Documentation of a trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
5. Patient has a diagnosis of ~~moderate to severe~~ juvenile idiopathic arthritis *with oligoarthritis*; with
    a. Documentation of a trial and inadequate response to intraarticular glucocorticoid injections and methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); *or* ~~and~~
6. *Patient has a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) with;*

a. *Documentation of a trial and inadequate response to methotrexate at a maximally tolerated dose (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or*

7. *Patient has a diagnosis of systemic juvenile idiopathic arthritis (sJIA).*

~~In addition to the above:~~
~~Requests for TNF Inhibitors:~~

1. ~~Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and~~
2. ~~Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less.~~

~~Requests for Interleukins:~~

1. ~~Medication will not be given concurrently with live vaccines.~~

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

Biologicals for Hidradenitis Suppurativa

Current Clinical Prior Authorization

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. Patients initiating therapy with a biological agent must:

1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and
2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and
3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and
4. Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.

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 3 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 (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. ~~Patients initiating therapy with a biological agent must:~~

1. ~~Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and~~
2. ~~Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and~~
3. ~~Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and~~
4. ~~Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.~~

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 ~~3~~ *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.

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. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. 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
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
    f. Patient will continue with skin care regimen and regular use of emollients; and
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. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
    b. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and
    c. 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], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. Two (2) 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. Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and
b. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
c. 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
d. 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; and

7. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and
    b. Patient has experienced severe to very severe pruritits, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    c. Patient has ≥ 20 nodular lesions (attach documentation); and
    d. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; and
8. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized 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. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. 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
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    ~~e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and~~
    f. Patient will continue with skin care regimen and regular use of emollients; and

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. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
    b. 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
    c. 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], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
    d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. *One (1)* ~~Two (2)~~ 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. Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and
    b. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
    c. 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
    d. 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; ~~and~~ *or*
7. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Is prescribed by, or in consultation with an allergist, immunologist, or dermatologist; and
    b. Patient has experienced severe to very severe pruritits, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    c. Patient has ≥ 20 nodular lesions (attach documentation); and
    d. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; and
8. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of a

positive response to therapy.

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

Febuxostat (Uloric)

Current Clinical Prior Authorization Criteria – *Recommendation to remove prior authorization criteria.*
Prior authorization (PA) is required for febuxostat (Uloric). Payment for febuxostat (Uloric) will only be considered for cases in which symptoms of gout still persist while currently using 300mg per day of a preferred allopurinol product unless documentation is provided that such a trial would be medically contraindicated.

Select Preventative Migraine Treatments

Current Clinical Prior Authorization
Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or
    b. Episodic Migraine, defined as:
        i. 4 to 14 migraine days per month for a minimum of 3 months; or
    c. Episodic Cluster Headache, defined as:
        i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
        ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and
        iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and
2. Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings and precautions; and
3. The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and
4. Patient has been evaluated for and does not have medication overuse headache; and
5. For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
6. For Episodic Cluster Headache, patient has documentation of

a. A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and
b. A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.

7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

<u>Proposed Clinical Prior Authorization</u> (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for select preventative migraine agents. Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent. Payment will be considered under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headache days per month for a minimum of 3 months; or
    b. Episodic Migraine, defined as:
        i. 4 to 14 migraine days per month for a minimum of 3 months; or
    c. Episodic Cluster Headache, defined as:
        i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
        ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and
        iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and
2. 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
3. The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and
4. Patient has been evaluated for and does not have medication overuse headache; and

5. For Episodic and Chronic Migraine, patient has documentation of ~~three~~ *two* trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with ~~a minimum of~~ two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
6. For Episodic Cluster Headache, patient has documentation of
    a. A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and
    b. A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

Hepatitis C Agents, Direct Acting Antivirals

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C; and
2. Patient's age and/or weight is within the FDA labeled age and/or weight; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and
7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
8. Patient has been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as SAMHSA-HRSA Center for Integrated

Health Solutions – Drug & Alcohol Screening Tools and the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and

9. Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drug and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling; and
10. HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and
11. DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; and
12. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a. Patient is not a pregnant female or male with a pregnant female partner; and
    b. Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c. Monthly pregnancy tests will be performed during treatment; and
13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the DAA; and
14. Documentation is provided for patients who are ineligible to receive ribavirin; and
15. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved; and
16. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
17. If patient is recently eligible for Iowa Medicaid and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
18. Lost or stolen medication replacement requests will not be authorized.
19. The 72-hour emergency supply rule does not apply to DAAs.

Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:

1. Patient must meet all criteria for treatment approval above; and
2. Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and
3. The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and
4. Patient has not been previously treated with and failed the requested DAA therapy; and
5. Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). *Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific*

populations. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C; and
2. ~~Patient's age and/or weight is within the FDA labeled age and/or weight~~; ~~and~~
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. ~~Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and~~
6. Patient's prior HCV DAA treatment history is provided (treatment naïve or treatment experienced); and
7. ~~If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and~~
8. ~~Patient has been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools and the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and~~
9. ~~Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drug and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling; and~~
10. ~~HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and~~
11. DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines *and patient's weight is provided* ~~including for indication and age~~; and
12. ~~For patients on a regimen containing ribavirin, the following must be documented on the PA form:~~
    a. ~~Patient is not a pregnant female or male with a pregnant female partner; and~~
    b. ~~Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and~~
    c. ~~Monthly pregnancy tests will be performed during treatment; and~~
13. ~~Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the DAA; and~~
14. ~~Documentation is provided for patients who are ineligible to receive ribavirin; and~~
15. ~~Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved; and~~
16. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
17. If patient is recently eligible for Iowa Medicaid and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
18. ~~Lost or stolen medication replacement requests will not be authorized.~~
19. The 72-hour emergency supply rule does not apply to DAAs.

Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:

1. Patient must meet all criteria for treatment approval above; and
2. ~~Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and~~
3. The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and
4. *HCV retreatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and*
5. Patient has not been previously treated with and failed the requested DAA therapy; and
6. Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Biologicals for Arthritis; Biologicals for Hidradenitis Suppurativa; Dupilumab (Dupixent); Select Preventative Migraine Treatments; and Hepatitis C Treatment, Direct Acting Antivirals, as well as the removal of PA criteria for Febuxostat (Uloric).

Sincerely,

Pamela Smith R.Ph.

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Iowa Medicaid

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