



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

Xhance® (fluticasone propionate 93 mg nasal spray)
Effective -02/19/2020

Prior Authorization Request Form

XHANCE (fluticasone propionate 93 mg nasal spray) is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older. This product is packaged with an Exhalation Delivery System designed for administration deep into the nasal passages.

Prior authorization requests for Xhance may be approved if the following criteria are met:

1. Must be prescribed by, or in consultation with, an ENT, allergist, or other suitable specialist; **AND**
2. Patient must meet all age and indication restrictions listed in the FDA label; **AND**
3. Member must have a diagnosis of nasal polyps which have been inadequately controlled after at least 3-months of therapy with any intranasal steroid.

Initial approval shall be for 90 days and continuation of coverage shall require documentation of reduction/elimination of nasal polyps and patient adherence to therapy.

References

- 1.) LexiComp monograph on Xhance (accessed 9/12/2019)
- 2.) Xhance package insert (revised: 09/2017)
- 3.) UpToDate review on the Clinical presentation, diagnosis, and treatment of nasal obstruction (updated 7/29/2019)



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Prior Authorization Criteria

DUPIXENT® (dupilumab)
Effective 02/19/2020

Prior Authorization Request Form

DUPIXENT is an interleukin-4 receptor alpha antagonist indicated:

- I. For the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. **DUPIXENT** can be used with or without topical corticosteroids.
- II. As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- III. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

I. For the Indication of Atopic Dermatitis, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with an allergist, immunologist or dermatologist; **AND**
2. Documented diagnosis of moderate to severe Atopic Dermatitis (AD). Documentation must include the affected BSA, areas of involvement and severity of symptoms; **AND**
3. The patient must be within the age range as recommended by the FDA label and indication; **AND**
4. Affected body surface area is greater than or equal to 10%; **AND**
5. Patient has failed to find relief of symptoms after a minimum of 30-day trials of all agents from the following list in the last 12 months:
 - a. Medium to High potency topical corticosteroid*
 - b. Elidel
 - c. Eucrisa
 - d. Tacrolimus

*Requirement for topical corticosteroid therapy will be excluded for patients with sensitive areas of involvement such as the face, skin folds or genitals.

Initial approval of Dupixent for atopic dermatitis will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response (including current affected BSA and severity of symptoms).

II. For the indication of Asthma, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**
2. The patient must be within the age range as recommended by the FDA label and indication; **AND**
3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND EITHER**



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4. Documentation must be supplied indicating one of the following:
 - a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level \geq 3%
OR
 - b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months
 - c. **OR** claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Dupixent for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

III. For the indication of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), prior authorization requests may be approved if the following criteria are met:

1. Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**
2. Member must have a diagnosis of CRSwNP which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid. If the member has not trialed Xhance intranasal steroid, then they must also fail 3-months of therapy with that product; **AND**
3. The patient must be within the approved age range according to the FDA label and indication; **AND**
4. Dupixent is only approvable as add-on therapy for CRSwNP.

Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Dupixent was supplementing).

References

- 1.) LexiComp monograph for dupliumab (accessed 09/09/2019)
- 2.) Dupixent package insert revision 06/2019
- 3.) GINA: Difficult-to-treat and Severe Asthma in adolescents and adults patients. V2.0 April 2019 (www.ginasthma.org)
- 4.) UpToDate literature review on the treatment of severe asthma in adolescents and adults (11/07/2018)
- 5.) UpToDate literature review on the treatment of atopic dermatitis (11/2018)
- 6.) <https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis/diagnosis-and-assessment/disease-severity-recommendations>
- 7.) <https://www.ecu.edu/cs-dhs/fammed/upload/Atopic-Dermatitis-Guidelines.pdf>
- 8.) [https://journal.chestnet.org/article/S0012-3692\(11\)60278-X/pdf](https://journal.chestnet.org/article/S0012-3692(11)60278-X/pdf) (Point: Is Measuring Sputum Eosinophils Useful in the Management of Severe Asthma? Yes) Chest/139/6/June,2011 p 1271-1273.
- 9.) [https://journal.chestnet.org/article/S0012-3692\(11\)60279-1/pdf](https://journal.chestnet.org/article/S0012-3692(11)60279-1/pdf) (Counterpoint: Is Measuring Sputum Eosinophils Useful in the Management of Severe Asthma? No, Not for the Vast Majority of Patients) Chest/139/6/June,2011 p 1273-1275.



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Office of Pharmacy Service
Prior Authorization Criteria

PCSK9 INHIBITORS
PRALUENT®(alirocumab) & REPATHA® (evolocumab)
Effective 02/19/2020

[Prior Authorization Request Form](#)

REPATHA is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).
- as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

PRALUENT is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- as adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C.

CRITERIA FOR APPROVAL

- 1) Patient must meet all age and indication restrictions imposed by the current FDA-approved label; **AND**
- 2) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL after an 8-week trial of either **atorvastatin 40 - 80 mg + ezetimibe** OR **rosuvastatin 20 - 40 mg + ezetimibe**. Note: If the patient failed to tolerate the first statin/ezetimibe combination, then they must be trialed on the second combination for 8-weeks or until intolerance occurs.

Initial approval will be for 90 days.

Additional coverage may be granted with documentation of efficacy supported by at least a 40% LDL-C reduction from pre-treatment level. Maintenance therapy may be requested by any willing prescriber.

REFERENCES

- 1) Repatha package insert revised 2/2019; Praluent package insert revised 4/2019
- 2) Lexi-Comp Clinical Application reviewed 5/02/2019
- 3) American Academy of Cardiology 2018 Guideline on the Management of Blood Cholesterol (updated June 2019)
- 4) AACE 2017 Guidelines: American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocrine Practice Vol 23 (Suppl 2) April 2017.
- 5) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
- 6) Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722
Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: <http://circ.ahajournals.org>.
- 7) Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.
- 8) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. *Diabetes Metab Syndr Obes*. 2011; 4: 155–166.



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Office of Pharmacy Service
Prior Authorization Criteria

EXONDYS 51® (eteplirsen)
Effective 02/19/2020

EXONDYS 51 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication was approved under the accelerated approval process and was based on an increase in dystrophin in skeletal muscle observed in some patients treated with EXONDYS 51. **A clinical benefit of EXONDYS 51 has not been established.** Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Exondys 51 may be billed as a Medical ("Buy & Bill") claim OR as a Pharmacy Point-of-Sale (POS) claim:

- Medical "Buy & Bill" under J1428 - Contact KEPRO, tel: (304) 343-9663/ fax (866) 209-9632
- Pharmacy POS - Contact RDTP, tel: (800) 847-3859/ fax (800) 531-7787

All requests require review by the Medical Director and may be approvable once the following criteria are met:

1. Patient must have a confirmed mutation of a DMD gene that is amenable to exon 51 skipping (chart notes required); **AND**
2. The patient must meet all label requirements as recommended by the FDA and the manufacturer; **AND**
3. Request must either be from a neurologist or from a physician who has provided documentation of a formal consultation with a neurologist; **AND**

Patient must be stabilized on corticosteroid therapy for at least 6 months prior to the request for coverage of Exondys 51. Documentation must be supplied detailing the prescribed steroid therapy and the patient must continue this therapy while receiving Exondys 51

NOTE: If the patient cannot take steroid therapy, clinical justification must be provided by the physician, otherwise the prior authorization request shall be immediately denied;

AND

4. The results of appropriate and validated baseline functional tests must be submitted with the initial request for therapy. These results will be considered valid only if taken after the patient has received corticosteroid therapy for at least 6 months.

Acceptable tests may include, **but are not limited to**, any of the following:

- a. Ambulatory patients: Six-minute walk test (6MWDT) (patient must achieve > 180 meters for approval.
- b. Non-ambulatory patients: Brooke Upper Extremity Function Scale (of 5 or less) **AND** a Forced Vital Capacity of $\geq 30\%$ of predicted value are required for approval.



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Other functional assessment tests may be accepted on a case-by-case basis at the discretion of the Medical Director. These tests must be quantitative in nature and accompanied with supporting documentation and references describing the test.

All prior authorization approvals are limited to 6 months at time and continuation of coverage requires the following conditions to be met:

- 1) Follow-up functional test results must show stabilization or improvement of patient function compared to baseline measures; **AND**
- 2) Patient must maintain 100% compliance with all scheduled therapy - Exondys 51 must be dosed once per week and maintenance steroid therapy must continue as prescribed by the physician. Failure to maintain compliance with prescribed therapy shall result in immediate discontinuation of coverage unless the disruption can be medically justified by the prescribing physician.

REFERENCES

- 1.) Exondys 51 Package Insert (Sarepta Therapeutics) – Revised 2/2018
- 2.) Lexicomp monograph for Exondys 51 – reviewed 5/10/2018
- 3.) Measures of Clinical Assessment in Patients with Duchenne Muscular Dystrophy (DMD)
<https://sarepta.appdataroom.com/download/v/bd16dff387135c4643386085c1bdc58fc508ef490459?ts=1582134595&sig=35e5f191eed1241b58063411fc49504f65bf63e7&trackingGuid=CD B061BF-A492-4090-A22E-2FADB6F9B100&groupId=4411>
- 4.) Birnkrant et al. Lancet Neurol. 2018 March; 17(3): 251-267. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management
- 5.) Mendell, JR et al. Ann Neurol 2016;79:257–271. Longitudinal Effect of Eteplirsen versus Historical Control on Ambulation in Duchenne Muscular Dystrophy
- 6.) Kinane, TB et al. Journal of Neuromuscular Diseases 5 (2018) 47–58 Long-Term Pulmonary Function in Duchenne Muscular Dystrophy: Comparison of Eteplirsen-Treated Patients to Natural History
- 7.) Kenji Rowel Q Lim, Rika Maruyama and Toshifumi Yokota *Drug Des Devel Ther.* 2017; 11: 533–545. Eteplirsen in the treatment of Duchenne muscular dystrophy.
- 8.) Clinical Trials:
 - a. <https://clinicaltrials.gov/ct2/show/NCT01396239?term=eteplirsen&rank=6>
 - b. <https://clinicaltrials.gov/ct2/show/NCT01540409>
 - c. **Ongoing confirmatory phase 3 trial:** An Open-Label, Multi-Center, Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsen in Duchenne Muscular Dystrophy (<https://clinicaltrials.gov/ct2/show/NCT02255552>)
Estimated study completion date May 1, 2019



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VYONDYS 53® (golodirsen)
Effective 02/19/2020

VYONDYS 53 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VYONDYS 53. **A clinical benefit of VYONDYS 53 has not been established.** Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

VYONDYS 53 is currently billable only as a Pharmacy Point-of-Sale (POS) claim:

- Pharmacy POS - Contact RDTP, tel: (800) 847-3859/ fax (800) 531-7787

All requests require review by the Medical Director and may be approvable once the following criteria are met:

1. Patient must have a confirmed mutation of a DMD gene that is amenable to exon 53 skipping (chart notes required); **AND**
2. The patient must meet all label requirements as recommended by the FDA and the manufacturer; **AND**
3. Baseline renal function must be evaluated, and documentation provided with the request for Vyondys 53; **AND**
4. Request must either be from a neurologist or from a physician who has provided documentation of a formal consultation with a neurologist; **AND**

Patient must be stabilized on corticosteroid therapy for at least 6 months prior to the request for coverage of Vyondys 53. Documentation must be supplied detailing the prescribed steroid therapy and the patient must continue this therapy while receiving Vyondys 53.

NOTE: If the patient cannot take steroid therapy, clinical justification must be provided by the physician, otherwise the prior authorization request shall be immediately denied;

AND

5. The results of appropriate and validated baseline functional tests must be submitted with the initial request for therapy. These results will be considered valid only if taken after the patient has received corticosteroid therapy for at least 6 months.

Acceptable tests may include, **but are not limited to**, any of the following:

- a. Ambulatory patients: Six-minute walk test (6MWDT) (patient must achieve > 180 meters for approval.



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- b. Non-ambulatory patients: Brooke Upper Extremity Function Scale (of 5 or less) **AND** a Forced Vital Capacity of $\geq 30\%$ of predicted value are required for approval.

Other functional assessment tests may be accepted on a case-by-case basis at the discretion of the Medical Director. These tests must be quantitative in nature and accompanied with supporting documentation and references describing the test.

All prior authorization approvals are limited to 6 months at time and continuation of coverage requires the following conditions to be met:

- 3) Follow-up functional test results must show stabilization or improvement of patient function compared to baseline measures; **AND**
- 4) The results of regular renal function tests (as recommended by the manufacturer*) must be supplied with every request for Vyondys 53; **AND**
- 5) Patient must maintain 100% compliance on all scheduled therapy - Vyondys 53 must be dosed once per week and maintenance steroid therapy must continue as prescribed by the physician. Failure to maintain compliance with prescribed therapy shall result in immediate discontinuation of coverage unless the disruption can be medically justified by the prescribing physician.

*Measurement of glomerular filtration rate (GFR) by 24-hour urine collection prior to initiation of therapy is recommended. Monthly monitoring for proteinuria by dipstick urinalysis and monitoring of serum cystatin C every three months is recommended. In the case of a confirmed dipstick proteinuria of 2+ or greater or elevated serum cystatin C, a 24-hour urine collection to quantify proteinuria and assess GFR should be performed.

REFERENCES

- 1.) Vyondys 53 Package Insert (Sarepta Therapeutics) – Revised 12/2019
- 2.) Lexicomp monograph for Vyondys 53 – reviewed 2/19/2020
- 3.) Drug Trials Snapshots: Vyondys 53 (<https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-vyondys-53>)
- 4.) Measures of Clinical Assessment in Patients with Duchenne Muscular Dystrophy (DMD) <https://sarepta.appdataroom.com/download/v/bd16dff387135c4643386085c1bdc58fc508ef490459?ts=1582134595&sig=35e5f191eed1241b58063411fc49504f65bf63e7&trackingGuid=CD B061BF-A492-4090-A22E-2FADB6F9B100&groupId=4411>
- 5.) Birnkrant et al. Lancet Neurol. 2018 March; 17(3): 251-267. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management



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LIPOTROPICS, OTHER (Non-statins)

FATTY ACIDS^{CL}		
<p>omega-3 acid ethyl esters VASCEPA (icosapent ethyl)</p>	<p>LOVAZA (omega-3-acid ethyl esters)</p>	<p>^{CL}All agents in this subclass require a prior authorization and an initial triglyceride level \geq 500 mg/dL.</p> <p>Additionally, Vascepa may be approved if the following criteria is met:</p> <ol style="list-style-type: none"> 1. The patient has an initial triglyceride level of \geq 150 mg/dL prior to start of therapy; AND 2. The patient has established cardiovascular disease or diabetes; AND 3. The patient is concomitantly receiving a statin.

HEPATITIS B TREATMENTS

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

<p>BARACLUDE SOLUTION (entecavir) * entecavir lamivudine HBV</p>	<p>adefovir BARACLUDE TABLET (entecavir) EPIVIR HBV (lamivudine) HEPSERA (adefovir) VELMIDY (tenofovir alafenamide fumarate)</p>	<p>*Baraclude solution will be authorized only for patients with documentation of dysphagia.</p>
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ANTIRETROVIRALS^{AP}

COMBINATION PRODUCTS – NUCLEOSIDE & NUCLEOTIDE ANALOG RTIS		
<p>DESCOVY (emtricitabine/tenofovir)</p>	<p>TRUVADA (emtricitabine/tenofovir)*</p>	<p>*Truvada shall be treated as preferred when prescribed for PrEP in members assigned female at birth. Truvada may also be approved over Descovy where guidelines clearly indicate superiority over Descovy (documentation may be required to support the request for PA).</p>



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HYPOGLYCEMICS, INSULIN AND RELATED AGENTS

CLASS PA CRITERIA: Non-preferred agents require a ninety (90) day trial of a pharmacokinetically similar agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

APIDRA (insulin glulisine)^{AP*}
 FIASP (insulin aspart)
 HUMALOG (insulin lispro)
HUMALOG JR KWIKPEN (insulin lispro)
HUMALOG KWIKPEN U-100 (insulin lispro)
HUMALOG MIX PENS (insulin lispro/lispro protamine)
 HUMALOG MIX VIALS (insulin lispro/lispro protamine)
 HUMULIN N VIAL (insulin)
 HUMULIN R U-500 VIAL (insulin)
HUMULIN R U-500 KWIKPEN (insulin)
 LANTUS (insulin glargine)
 LEVEMIR (insulin detemir)
 NOVOLOG (insulin aspart)
 NOVOLOG MIX (insulin aspart/aspart protamine)
 TRESIBA (insulin degludec)
 TRESIBA FLEXTOUCH (insulin degludec)

ADMELOG (insulin lispro)
 AFREZZA (insulin)^{CL}
 BASAGLAR (insulin glargine)
 HUMULIN PENS (insulin)
HUMULIN R VIAL (insulin)
HUMULIN 70/30 (insulin)
 NOVOLIN (insulin)
 SOLIQUA (insulin glargine/lixisenatide)**
 TOUJEO SOLOSTAR (insulin glargine)***
 XULTOPHY (insulin degludec/liraglutide)**

*Apidra will be authorized if the following criteria are met:

1. Patient is four (4) years of age or older; **and**
2. Patient is currently on a regimen including a longer acting or basal insulin, **and**
3. Patient has had a trial of a similar preferred agent, Novolog or Humalog, with documentation that the desired results were not achieved..

** Non-preferred insulin combination products require that the patient must already be established on the individual agents at doses not exceeding the maximum dose achievable with the combination product, and require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a combination of preferred single-ingredient agents.

***Toujeo Solostar and Toujeo Max Solostar may be approved only for:

- 1.) Patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia.
- OR**
- 2.) Patients who currently require over 200 units per day of long-acting insulin.