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#### Pharmacy Prior Authorization Non-Formulary and Prior Authorization Guidelines

#### Scroll down to see PA Criteria by drug class, or Ctrl+F to search document by drug name

PA guideline	Requirements	Duration of Approval if Requirements Are Met
Medications requiring Prior Authorization	Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non- Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.	As documented in the individual guideline
Medications requiring Step Therapy	<ul> <li>Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.</li> <li>To find agents that have a Step Therapy requirement, go to our health plan website and use the formulary search tool.</li> <li>ABH of Maryland Formulary Search Tool</li> </ul>	Initial Approval: • Indefinite
Bonjesta Doxylamine Succinate and Pyridoxine Hydrochloride (Diclegis) <sup>i</sup>	<ul> <li>May be authorized when the following criteria are met:         <ul> <li>Member is at least 18 years of age</li> <li>Diagnosis of nausea and vomiting in pregnancy</li> <li>Inadequate response or intolerable side effects to dietary and lifestyle changes                 <ul></ul></li></ul></li></ul>	Initial Approval:         3 months         Renewal:         3 months         Requires:         • Documentation member is still pregnant and continues to have nausea and

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	<ul> <li>Pyridoxine is available as a single agent and recommended dose 10-25mg orally every six to eight hours.</li> <li>Doxylamine is available as over-the-counter and as prescription products, with recommended dose as one-half 25mg over-the-counter tablet, or two chewable 5mg prescription tablets</li> <li>For Bonjesta: Use of generic prescription doxylamine succinate and pyridoxine hydrochloride has not achieved adequate treatment response</li> </ul>	vomiting symptoms <b>Quantity Level Limit</b> : <u>Diclegis or generic Doxylamine Succinate and</u> <u>Pyridoxine Hydrochloride</u> : 4 tablets per day <u>Bonjesta</u> : 2 tablets per day
COVID-19 Prescribing	<ul> <li>Kaletra may be authorized when the following criteria are met:</li> <li>Documented diagnosis of COVID-19 (coronavirus disease 2019) if the medication is not being used to treat human immunodeficiency virus (HIV)</li> <li>Total duration of therapy will not exceed 14 days</li> <li>Hydroxychloroquine and Chloroquine may be authorized when the following criteria are met:</li> <li>Documented diagnosis of COVID-19 (coronavirus disease 2019) if medication is not being used to treat rheumatoid arthritis or lupus</li> <li>Will be used in combination with azithromycin</li> <li>Total duration of therapy will not exceed 10 days</li> </ul>	<ul> <li><u>Approvals:</u> <ul> <li>Kaletra – 14 days</li> <li>Hydroxychloroquine and chloroquine – 10 days</li> </ul> </li> <li><u>Quantity Level Limits:</u> <ul> <li>Members are limited to one fill of each medication every 60 days</li> </ul> </li> </ul>
Non-Stimulant ADHD Medications Guanfacine ER Clonidine ER 0.1mg Kapvay 0.2mg	For recipients 6 – 17 years old, the extended release forms of guanfacine (Intuniv) and clonidine (Kapvay) are included on the mental health formulary and billed fee-for-service. For individuals not in this age range, guanfacine ER (Intuniv) and clonidine ER (Kapvay) continue to be part of the MCO pharmacy benefit and will be reviewed based on past failure of other agents used to treat ADHD.	Initial Approval: • Indefinite

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Opioid Analgesics	<ul> <li>7 day supply first fill for opioid naïve members</li> <li>All opioids will be subject to a &gt; 90 cumulative morphine milligram equivalent per day edit (includes both Long and short acting opioids).</li> <li>Members who are receiving opioids for the following will be exempted from these requirements for formulary agents: <ol> <li>Cancer treatment (patients who are receiving pain medication as part of their active cancer treatment)</li> <li>Sickle Cell Disease</li> <li>Hospice or Palliative Care (Diagnosis code: Z51.5)</li> <li>Long Term Care – if in long term care facility</li> </ol> </li> <li>Long acting opioids and cumulative dose greater than 90 morphine milligram equivalents (MME/day) will require prior authorization and must meet following general criteria for approval (Formulary and Non-formulary):</li> <li>Member who is being discharged from the hospital or Emergency Room (ER), acute care inpatient Hospital (Hospital), Ambulatory Surgery Center (ASC), prescribers must meet following requirements: <ol> <li>Prescriber has reviewed controlled substance prescriptions in a Prescription Drug monitoring program (e.g. CRISP- Chesapeake Regional Information System)</li> <li>Documentation of daily MME/day. Provider should provide rationale for dose exceeding 90 MME/day.</li> </ol> </li> </ul>	Initial/Renewal Approval duration:         • For Inpatient Hospital (Hospital), Ambulatory Surgery Center (ASC), and Emergency Room (ER) Prescribers: 1 month (30 days)         • Others: 6 months

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Requirements	Duration of Approval if Requirements Are
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<ul> <li>Prescriber has discussed the risks/benefits associated with opioid use with patient/patient's household</li> <li>Prescriber attest that patient is exempt from need for a Patient-Prescriber Pain Management/Opioid Treatment Agreement and random UDS, because he/she is being discharged from the Hospital/ASC/ER and opioid treatment prescribed by the discharging provider will be for less than 30 days or the need for further opioid use will be re-evaluated by an Outpatient provider within 30 days.</li> <li>Prescriber attests that the health benefit outweighs the risk of treatment with prescribed opioid treatment</li> <li>Member who are receiving opioid treatment for ongoing care must meet following requirements (i.e., requests by an outpatient provider):</li> <li>Prescriber has reviewed controlled substance prescriptions in a Prescription Drug monitoring program (e.g. CRISP- Chesapeake Regional Information System)         <ul> <li>Documentation of daily MME/day. Provider should provide rationale for dose exceeding 90 MME/day.</li> <li>Prescriber attests that patient-prescriber pain management contract has been signed and is in patient's medical records.</li> <li>Prescriber attests that patient has/will have random urine drug screens (UDS) before and during treatment.</li> <li>Prescriber has provided or offered a prescription for naloxone to patients or patient's household</li> <li>Prescriber attests that the health benefit outweighs the risk of treatment with prescribed opioid treatment.</li> </ul> </li> </ul>	
<ul> <li>For treatment of moderate to severe chronic pain</li> </ul>	
	<ul> <li>Prescriber has discussed the risks/benefits associated with opioid use with patient/patient's household</li> <li>Prescriber attest that patient is exempt from need for a Patient-Prescriber Pain Management/Opioid Treatment Agreement and random UDS, because he/she is being discharged from the Hospital/ASC/ER and opioid treatment prescribed by the discharging provider will be for less than 30 days or the need for further opioid use will be re-evaluated by an Outpatient provider within 30 days.</li> <li>Prescriber attests that the health benefit outweighs the risk of treatment with prescribed opioid treatment</li> <li>Member who are receiving opioid treatment for ongoing care must meet following requirements (i.e., requests by an outpatient provider):</li> <li>Prescriber has reviewed controlled substance prescriptions in a Prescription Drug monitoring program (e.g. CRISP- Chesapeake Regional Information System)         <ul> <li>Documentation of daily MME/day. Provider should provide rationale for dose exceeding 90 MME/day.</li> </ul> </li> <li>Prescriber attests that patient-prescriber pain management contract has been signed and is in patient's medical records.</li> <li>Prescriber attests that patient has/will have random urine drug screens (UDS) before and during treatment.</li> <li>Prescriber has provided or offered a prescription for naloxone to patients or patient's household</li> <li>Prescriber attests that the health benefit outweighs the risk of treatment with prescribed opioid treatment.</li> </ul>

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	<ul> <li>Member had inadequate response (at least 2 weeks trial and at maximum tolerated doses) or intolerance to at least TWO formulary long-acting opioids (i.e., fentanyl patch, morphine sulfate ER, methadone)</li> <li>In addition, criteria for Non-formulary Long-acting opioids:         <ul> <li>For treatment of moderate to severe chronic pain</li> <li>Member had inadequate response (at least 2 weeks trial and at maximum tolerated doses) or intolerance to oxymorphone ER AND at least TWO other formulary long-acting opioids</li> </ul> </li> <li>Nucynta ER:         <ul> <li>Member has diagnosis of diabetic peripheral neuropathy</li> <li>In addition, criteria for Non-formulary short-acting opioids:</li> </ul> </li> </ul>	
	Patient had inadequate response or intolerance to THREE formulary short-acting opioids	
Savella	Approved for patients who have a diagnosis of fibromyalgia	Initial Approval: Indefinite
Tranexamic Acid Tablets <sup>ii</sup>	<ul> <li>Member is 12 years of age or older</li> <li>Treatment is for cyclic heavy menstrual bleeding</li> <li>Prescriber attestation that member has no fibroids, or fibroids are less than 3 cm in size</li> <li>There was inadequate response, intolerable side effect, or contraindication to one oral Non-Steroidal Anti-inflammatory Drug (NSAID)</li> <li>Member had inadequate response, intolerable side effect, or contraindication to one of the following:         <ul> <li>Oral hormonal cycle control combinations</li> <li>Oral progesterone</li> <li>Progesterone-containing intrauterine device (IUD)</li> </ul> </li> </ul>	Initial Approval:         90 days         Renewal Approval:         6 months         Requires:         • Reduction in menstrual blood loss         Quantity Level Limit:         • Menstrual bleeding:
	<ul> <li>Medroxyprogesterone depot</li> </ul>	30 tablets per 30 days

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	<ul> <li>Member does not have history of thrombosis or thromboembolism (including retinal vein or artery occlusion)</li> <li>Approved for treatment and prevention of acute bleeding episodes, such as dental surgery, in members with hemophilia.</li> </ul>	<ul> <li>Hemophilia: 84 tablets per 30 days</li> </ul>

#### <sup>i</sup> Diclegis & Bonjesta References

- 1. Nausea and vomiting of pregnancy. Practice Bulletin No. 189. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018; 131(1):e15-e30. https://journals.lww.com/greenjournal/Fulltext/2018/01000/ACOG\_Practice\_Bulletin\_No\_189\_Nausea\_And.39.aspx
- 2. Diclegis<sup>®</sup> (doxylamine succinate and pyridoxine hydrochloride). [Prescribing Information]. Bryn Mawr, PA. Duchesnay Inc; Revised September 2018.
- 3. Bonjesta® (doxylamine succinate and pyridoxine hydrochloride). [Prescribing Information]. Bryn Mawr, PA. Duchesnay Inc; Revised June 2018.
- 4. Gold Standard, Inc. Diclegis. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed October 15, 2019.
- 5. Gold Standard, Inc. Bonjesta. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed October 15,<sup>t</sup>, 2019.
- 6. Facts & Comparisons eAnswers. Drug Facts and Comparisons. Indianapolis, IN: Wolters Kluwer Health; 2013. http://online.factsandcomparisons.com/. Accessed October 15, 2019

#### <sup>II</sup> Tranexamic acid References

- 1. National institute for health and care excellence, Heavy menstrual bleeding: assessment and management, <a href="https://www.nice.org.uk/guidance/ng88/resources/heavy-menstrual-bleeding-assessment-and-management-pdf-1837701412549">https://www.nice.org.uk/guidance/ng88/resources/heavy-menstrual-bleeding-assessment-and-management-pdf-1837701412549</a>. Accessed November 26th, 2019
- 2. Hemostatic agents, World Federation of Hemophilia. (2012). http://www1.wfh.org/publications/files/pdf-1497.pdf. Accessed November 26th, 2019
- 3. Lysteda® [package insert] March 2016. Parsippany, NJ. Ferring Pharmaceuticals, Inc. Retrieved from <a href="http://www.ferringusa.com/wp-content/uploads/2016/07/LystedaPl\_3.2016.pdf">http://www.ferringusa.com/wp-content/uploads/2016/07/LystedaPl\_3.2016.pdf</a>. Accessed December 24, 2019.
- 4. Clinical pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from <a href="http://clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=1591&sec=monindi&t=0">http://clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=1591&sec=monindi&t=0</a>. Accessed November 28th, 2019

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