Hemophilia Factor IX Medical Drug Criteria Program Summary

POLICY REVIEW CYCLE

Effective Date 11-01-2024

Date of Origin

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
AlphaNine SD® (Coagulation Factor IX [Human]) Powder for reconstitution for intravenous use	• The prevention and control of bleeding in patients with Factor IX deficiency due to hemophilia B. AlphaNine SD contains low, non-therapeutic levels of Factors II, VII, and X, and, therefore, is *not* indicated for the treatment of Factor II, VII or X deficiencies. This product is also *not* indicated for the reversal of coumarin anticoagulant-induced hemorrhage, nor in the treatment of hemophilia A patients with inhibitors to Factor VIII	Human Plasma-derived Coagulation Factor IX Concentrates	1
Alprolix® (Coagulation Factor IX [recombinant], Fc Fusion protein) Powder for solution for intravenous use	• Adults and children with hemophilia B for: ○ On-demand treatment and control of bleeding episodes ○ Perioperative management of bleeding ○ Routine prophylaxis to reduce the frequency of bleeding episodes Limitations of Use: Alprolix is not indicated for induction of immune tolerance in patients with hemophilia B	Recombinant Factor IX Concentrates	2
BeneFIX® (Coagulation Factor IX [recombinant]) Powder for reconstitution for intravenous use	• Adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for: ○ On-demand treatment and control of bleeding episodes ○ Peri-operative management of bleeding ○ Routine prophylaxis to reduce the frequency of bleeding episodes Limitations of Use: BeneFIX is not indicated for induction of immune tolerance in patients with hemophilia B	Recombinant Factor IX Concentrates	3
Idelvion® (Coagulation Factor IX	• Children and adults with Hemophilia B (congenital Factor IX deficiency) for: ○ On-demand treatment and control of bleeding episodes ○ Perioperative management of bleeding	Recombinant Factor IX Concentrates	4

Agent(s)	FDA Indication(s)	Notes	Ref#
[recombinant]) Lyophilized powder for solution for intravenous use	○ Routine prophylaxis to reduce the frequency of bleeding episodes Limitations of Use: Idelvion is not indicated for immune tolerance induction in patients with Hemophilia B.		
Ixinity® (Coagulation Factor IX [recombinant]) Lyophilized powder for solution for intravenous use	• Adults and children greater than or equal to 12 years of age with hemophilia B for: ○ On-demand treatment and control of bleeding episodes ○ Perioperative management ○ Routine prophylaxis to reduce the frequency of bleeding episodes Limitations of Use: Ixinity is not indicated for induction of immune tolerance in patients with hemophilia B.	Recombinant Factor IX Concentrates	5
Profilnine® (Factor IX complex) Lyophilized concentrate for reconstitution for intravenous use	• The prevention and control of bleeding in patients with factor IX deficiency (hemophilia B) Profilnine SD contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of VII deficiency	Human Plasma-derived Coagulation Factor IX Concentrates	7
Rebinyn® (Coagulation Factor IX [recombinant], GlycoPEGylated) Powder for solution for intravenous use	• Adults and children with hemophilia B (congenital Factor IX deficiency) for: ○ On-demand treatment and control of bleeding episodes ○ Perioperative management of bleeding ○ Routine prophylaxis to reduce the frequency of bleeding episodes Limitations of Use: Rebinyn is not indicated for immune tolerance induction in patients with hemophilia B	Recombinant Factor IX Concentrates	8
Rixubis® (Coagulation Factor IX [recombinant]) Lyophilized powder for solution for intravenous use	• Adults and children with hemophilia B for: ○ On-demand treatment and control of bleeding episodes ○ Perioperative management of bleeding ○ Routine prophylaxis to reduce the frequency of bleeding episodes Rixubis is not indicated for induction of immune tolerance in patients with Hemophilia B	Recombinant Factor IX Concentrates	9

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Hemophilia B	Hemophilia B, also called Factor IX (FIX) deficiency or Christmas disease, is a genetic disorder caused by missing or defective Factor IX, a clotting protein. Although it is passed down from parents to children, about 1/3 of cases are caused by a spontaneous mutation.(10) The main goal of any therapy is to completely prevent bleeding. The current World Hemophilia Federation Guidelines for the Management of Hemophilia state:(14) • Both virus-inactivated plasma-derived and recombinant clotting factor concentrates (CFCs), as well as other hemostasis products when appropriate can be used for treatment of bleeding and prophylaxis in people with hemophilia • Prophylaxis is the standard of care for people with severe hemophilia, and for some people with moderate hemophilia or for those with a severe bleeding phenotype and/or a high risk of spontaneous life-threatening bleeding • Episodic CFC replacement should not be considered a long-term option for the management of hemophilia as it does not alter its natural history of spontaneous bleeding and related complications • Emerging therapies in development with alternative modes of delivery (e.g., subcutaneous injection) and novel targets may overcome the limitations of standard CFC replacement therapy (i.e., need for intravenous administration, short half-life, risk of inhibitor formation) • The development of gene therapies for hemophilia has advanced significantly, with product registration likely in the near future • Gene therapy should make it possible or some people with hemophilia to aspire to and attain much better health outcomes and quality of life than that attainable with currently available hemophilia therapies • Given the ongoing advances transforming the hemophilia treatment landscape, it is important to establish systems to constantly monitor developments in emerging and gene therapies for hemophilia and make them available as soon as possible following approval by regulatory authorities The MASAC suggests the number of doses required for provision of home therapy varies greatly and is dependent upon the type of hemophilia (FVIII, FIX), the level of severity (severe, moderate, mild), the presence of an inhibitor, the prescribed regimen (on-demand, prophylaxis, immune tolerance), the number of bleeding episodes experienced regardless of the prescribed regimen, individual pharmacokinetics, the products utilized, and the level of physical activity. For patients on prophylaxis, a minimum of one major dose and two minor doses should be available in addition to the prophylactic doses utilized monthly. For patients with severe or moderate hemophilia treated on-demand, the number of doses required to be available at home may be based upon historical bleeding patterns, with at least one major and two minor doses added to assure a level of safety.(11) A major dose is defined as a correction of clotting factor that achieves a level of 60-100+% clotting factor activity that is utilized to treat a bleeding episode that is expected to require a higher hemostatic level such as when bleeds occur in a target joint, or joint/area with a risk of significant sequelae (e.g., hip, head, GI bleed, etc.). A minor dose is defined as a correction of clotting factor that achieves a level of 30-60% clotting factor activity that is utilized to treat a bleeding episode that is treated early, in a non-critical area and treatable with a lower hemostatic level (e.g., early non-major joints, small muscle bleeds, and skin/soft tissue, etc.).(11) The Medical and Scientific Advisory Council (MASAC) and National Hemophilia Foundation (NHF) guidelines on treatment of hemophilia B recommend Recombinant FIX (rFIX) products over plasma-derived products as the treatment of choice.(13)

	In view of the demonstrated benefits of prophylaxis (regular/scheduled administration of clotting factor concentrate to prevent bleeding) begun at a young age in persons with hemophilia A or B, MASAC recommends that prophylaxis be considered standard of care therapy for individuals with severe hemophilia B (factor IX less than 1%) including those with inhibitors. Prophylactic therapy may also be considered for persons with moderate and mild hemophilia with a severe phenotype. Prophylactic therapy should be instituted early (prior to the onset of frequent bleeding).(12)

Safety	• **AlphaNine SD** has no known FDA labeled contraindications(1)
	• **Alprolix** is contraindicated in:(2)
	  ○ Individuals who have a known history of hypersensitivity reactions, including anaphylaxis, to the product or its excipients
	• **BeneFIX** is contraindicated in:(3)
	  ○ Patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein
	• **Idelvion** is contraindicated in:(4)
	  ○ Patients who have had life-threatening hypersensitivity reactions to Idelvion or its components, including hamster proteins
	• **Ixinity** is contraindicated in:(5)
	  ○ Patients with known hypersensitivity to Ixinity or its excipients, including hamster protein
	• **Profilnine** has no known FDA labeled contraindications(7)
	• **Rebinyn** is contraindicated in:(8)
	  ○ Patients who have known hypersensitivity to Rebinyn or its components, including hamster proteins
	• **Rixubis** is contraindicated in:(9)
	  ○ Known hypersensitivity to Rixubis or its excipients including hamster protein
	  ○ Disseminated intravascular coagulation (DIC)
	  ○ Signs of fibrinolysis

REFERENCES

Number	Reference
1	AlphaNine SD prescribing information. Grifols USA, LLC. November 2022.
2	Alprolix prescribing information. Bioverativ Therapeutics Inc. May 2023.
3	BeneFIX prescribing information. Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC. November 2022.
4	Idelvion prescribing information. CSL Behring Lengnau AG. June 2023.
5	Ixinity prescribing information. Medexus Pharma, Inc. November 2022.
6	Reference non longer used.
7	Profilnine prescribing information. Grifols USA, LLC. November 2022.
8	Rebinyn prescribing information. Novo Nordisk. August 2022.
9	Rixubis prescribing information. Takeda Pharmaceuticals America, Inc. March 2023.
10	National Hemophilia Foundation. Bleeding Disorders A-Z/Types/Hemophilia B. Accessed at: https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b .
11	Medical and Scientific Advisory Committee. MASAC recommendation regarding doses of clotting factor concentrate in the home. MASAC Document #242. June 2016.
12	Medical and Scientific Advisory Committee. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. MASAC Document #267. April 2022.
13	Medical and Scientific Advisory Council (MASAC) MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Document #280. August 2023.
14	Srivastave A, Santagostino E, Dougall A, et al. World Federation of Hemophilia Guidelines for the Management of Hemophilia. 3rd edition. August 2020.

Number	Reference
15	Reference no longer used

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

HCPC Codes	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
J7193	Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7201	Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7195	Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7202	Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7195 ; J7213	Ixinity	Coagulation Factor IX (Recombinant) For Inj ; coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7194	Profilnine	Factor IX Complex For Inj ; factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7203	Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
J7200	Rixubis	Coagulation Factor IX (Recombinant) For Inj ; coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx
Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx
Ixinity	Coagulation Factor IX (Recombinant) For Inj ; coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx
Profilnine	Factor IX Complex For Inj ; factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx
Rixubis	Coagulation Factor IX (Recombinant) For Inj ; coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alphanine sd	coagulation factor ix for inj	500 UNIT	Commercial ; HIM ; ResultsRx
Alphanine sd	coagulation factor ix for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Alphanine sd	coagulation factor ix for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Alphanine sd	coagulation factor ix for inj	1500 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	3000 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	4000 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	500 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	2000 UNIT	Commercial ; HIM ; ResultsRx
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	250 UNIT	Commercial ; HIM ; ResultsRx
Benefix	coagulation factor ix (recombinant) for inj kit	3000 UNIT	Commercial ; HIM ; ResultsRx
Benefix	coagulation factor ix (recombinant) for inj kit	500 UNIT	Commercial ; HIM ; ResultsRx
Benefix	coagulation factor ix (recombinant) for inj kit	2000 UNIT	Commercial ; HIM ; ResultsRx
Benefix	coagulation factor ix (recombinant) for inj kit	250 UNIT	Commercial ; HIM ; ResultsRx
Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT	Commercial ; HIM ; ResultsRx
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	500 UNIT	Commercial ; HIM ; ResultsRx
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	3500 UNIT	Commercial ; HIM ; ResultsRx
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	2000 UNIT	Commercial ; HIM ; ResultsRx
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	250 UNIT	Commercial ; HIM ; ResultsRx
Ixinity	coagulation factor ix (recombinant) for inj	1500 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	250 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	250 UNIT	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	500 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	2000 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	3000 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	2000 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	Coagulation Factor IX (Recombinant) For Inj 3000 Unit	3000 UNIT	Commercial ; HIM ; ResultsRx
Ixinity ; Rixubis	Coagulation Factor IX (Recombinant) For Inj 500 Unit	500 UNIT	Commercial ; HIM ; ResultsRx
Profilnine	factor ix complex for inj	500 UNIT	Commercial ; HIM ; ResultsRx
Profilnine	factor ix complex for inj	1000 UNIT	Commercial ; HIM ; ResultsRx
Profilnine	factor ix complex for inj	1500 UNIT	Commercial ; HIM ; ResultsRx
Rebinyn	coagulation factor ix recomb glycopegylated for inj	500 UNIT	Commercial ; HIM ; ResultsRx
Rebinyn	coagulation factor ix recomb glycopegylated for inj	2000 UNIT	Commercial ; HIM ; ResultsRx
Rebinyn	coagulation factor ix recomb glycopegylated for inj	3000 UNIT	Commercial ; HIM ; ResultsRx
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. BOTH of the following:
      1. The patient has a diagnosis of hemophilia B (also known as Factor IX deficiency, Christmas disease) AND ONE of the following:
         A. The patient is currently experiencing a bleed AND BOTH of the following:
            1. The patient is out of medication **AND**
            2. The patient needs to receive a ONE TIME emergency supply of medication **OR**

Module	Clinical Criteria for Approval
	B. BOTH of the following: 1. The requested agent is being used for ONE of the following: A. Prophylaxis **OR** B. On-demand use for bleeds **OR** C. Peri-operative management of bleeding **AND** 2. If the client has preferred agent(s) then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to the preferred agent(s) **OR** C. The patient has an intolerance, or hypersensitivity to ALL of the preferred agent(s) **OR** D. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) **AND** 2. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** C. Inhibitor status **AND** D. Intended use/regimen: prophylaxis, on-demand, peri-operative **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program **OR** B. There is support for the use of more than one unique Factor IX agent (medical records required) **AND** 6. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested quantity (dose) is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) **OR** B. There is support for exceeding the appropriate quantity limit based on the FDA labeled dose and/or intended use (medical records required) **Length of Approval:** One time emergency use: up to 2 weeks, Peri-operative dosing: 1 time per request, On-demand: up to 3 months, Prophylaxis: up to 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Medical Drug Review process (if current request is for a ONE TIME emergency use or the patient ONLY has previous approvals for emergency use, must use Initial Evaluation) (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND**

Module	Clinical Criteria for Approval
	2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** C. Inhibitor status **AND** D. Intended use/regimen: (e.g., prophylaxis, on-demand, peri-operative) **AND** 5. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. There is support for the patient having more than 5 on-demand doses on hand **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program **OR** B. There is support for the use of more than one unique Factor IX agent (medical records required) **AND** 7. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested quantity (dose) is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) **OR** B. There is support for exceeding the appropriate quantity limit based on the FDA labeled dose and/or intended use (medical records required) **Length of Approval:** On-demand: up to 3 months, Peri**-**operative dosing: 1 time per request, Prophylaxis: up to 12 months

