MEDICATION POLICY:

Anticoagulants (Oral)

Generic Name: Anticoagulants (Oral)

Therapeutic Class or Brand Name: Anticoagulants (Oral)

Applicable Drugs (if Therapeutic Class): Bevyxxa® (betrixaban), Eliquis® (apixaban), Pradaxa® (dabigatran), Savaysa® (edoxaban), Xarelto® (rivaroxaban).

GPI Code: 8337001000, 8337001820, 8333703020, 8337003020, 8337006000

Preferred: Eliquis® (apixaban), Xarelto® (rivaroxaban).

Non-preferred: Bevyxxa® (betrixaban), Pradaxa® (dabigatran), Savaysa® (edoxaban).

Date of Origin: 6/1/2013

Date Last Reviewed / Revised: 1/10/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through F AND must meet criteria listed under applicable diagnosis:

   A. Nonvalvular atrial fibrillation.

   B. DVT or PE Treatment.

   C. Reduction in the Risk of Recurrence of DVT and of PE.

   D. Hip or Knee Replacement Surgery Prophylaxis of DVT.

   E. Venous Thromboembolism (VTE) Prophylaxis AND criteria 1 and 2 are met:

      1. Documentation that patient has been hospitalized for an acute medical illness.

      2. Documentation that patient is at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.

   F. Reduction in the risk of cardiovascular death, myocardial infarction (MI) and stroke due to chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

II. Minimum age requirement: 18 years old.

III. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Active pathological bleeding.
- Prosthetic heart valves.
- Savaysa® is not recommended in patients with moderate to severe mitral stenosis.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Bevyxxa®: 30 capsules per 30 days.
- Eliquis®: 60 tablets per 30 days.
    - If being prescribed for DVT or PE treatment, 28 tablets may be authorized for the first 7 days of treatment, followed by 60 tablets per 30 days thereafter.
- Pradaxa: 60 capsules per 30 days.
- Savaysa®: 30 tablets per 30 days.
- Xarelto®:
    - 2.5mg tablets: 60 tablets per 30 days.
    - 10mg, 15mg, 20mg tablets: 30 tablets per 30 days;
        - If being prescribed for DVT or PE treatment, 42 tablets may be authorized for the first 21 days of treatment, followed by 30 tablets per 30 days thereafter.

Approval Length

- **Authorization:**
    - Hip Replacement Surgery Prophylaxis of DVT: One time for a total of 35 days.
    - Knee Replacement Surgery Prophylaxis of DVT: One time for a total of 12 days.
    - Venous Thromboembolism (VTE) Prophylaxis: One time for a total of 42 days.
    - All other Covered Uses: 1 year.
- **Re-Authorization:**
    - Hip or Knee Replacement Surgery Prophylaxis of DVT: N/A
    - Venous Thromboembolism (VTE) Prophylaxis: N/A
    - All other Covered Uses: An updated letter of medical necessity or progress notes to confirm that current medical necessity criteria are met and that the medication is effective.

Appendix

- N/A

REFERENCES

1. Medi-Span®.
2. http://packageinserts.bms.com/pi/pi_eliquis.pdf .
3. http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing%20Information/PIs/Pradaxa/Pradaxa.pdf .
4. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf .
5. http://dsi.com/prescribing-information-portlet/getPIContent?productName=Savaysa&inline=true .
6. http://www.bevyxxa.com/docs/Bevyxxa-Full-Prescribing-Information.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/10/2020	1. **Deleted** obsolete URLs "https://www.bmchp.org/I-Am-A/Member/Get-Prescriptions/Drug-Finder/QHP" and "http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Xarelto%20PA%20V3.pdf" **under References.** 2. **Changed** obsolete URL "https://www.xarelto-us.com/shared/product/xarelto/prescribing-information.pdf" **to** "http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf " **under References.** 3. **Changed obsolete URL "**http://www.bevyxxa.com/docs/Bevyxxa-Full-Prescribing-Information.pdf **" to "**http://www.bevyxxa.com/docs/Bevyxxa-Full-Prescribing-Information.pdf" **under References.**
12/12/2018	4. **Added** item F under Prior Authorization Criteria Roman numeral I: F. Reduction in the risk of cardiovascular death, myocardial infarction (MI) and stroke due to chronic coronary artery disease (CAD) or peripheral artery disease (PAD). • **Changed** under Quantity/Days Supply Restrictions section **from:** Xarelto®: 30 tablets per 30 dayhttps://www.xarelto-us.com/shared/product/xarelto/prescribing-information.pdfs **to** Xarelto®: o 2.5mg tablets: 60 tablets per 30 days o 10mg, 15mg, 20mg tablets: 30 tablets per 30 days; ▪ If being prescribed for DVT or PE treatment, 42 tablets may be authorized for the first 21 days of treatment, followed by 30 tablets per 30 days thereafter.

	5. **Changed** Reference #6 **from**: https://www.xarelto-us.com/shared/product/xarelto/prescribing-information.pdf **to:** http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf .
10/9/2018	1. **Changed** obsolete URL in Reference #1 (http://www.bmchp.org/app_assets/anticoagulantsoral_20130430t082106_en_web_019fbf5d61c24c6cba9333063c4b09ef.pdf) to https://www.bmchp.org/I-Am-A/Member/Get-Prescriptions/Drug-Finder/QHP . 2. **Added** registered trademark symbol to reference #3 "Medi-Span". 3. **Changed** obsolete URL in Reference #8 (http://www.bevyxxa.com/docs/Bevyxxa-Full-Prescribing-Information.pdf) to https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208383s000lbl.pdf .
12/2/2017	1. **Added** "Bevyxxa® (betrixaban)" **following** "Non-Preferred" **under Applicable Drugs**. 2. **Added** "8337001820" **following GPI Code**. 3. **Changed** "I. Documented diagnosis of one of the following conditions A through D: A. Nonvalvular atrial fibrillation; B. DVT or PE Treatment; C. Reduction in the Risk of Recurrence of DVT and of PE; D. Hip or Knee Replacement Surgery Prophylaxis of DVT" **to** "I. Documented diagnosis of one of the following conditions A through E AND must meet criteria listed under applicable diagnosis: A. Nonvalvular atrial fibrillation; B. DVT or PE Treatment; C. Reduction in the Risk of Recurrence of DVT and of PE; D. Hip or Knee Replacement Surgery Prophylaxis of DVT; E. Venous Thromboembolism (VTE) Prophylaxis AND criteria 1 and 2 are met: 1. Documentation that patient has been hospitalized for an acute medical illness; Documentation that patient is at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE" **under Prior Authorization Criteria**. 4. **Added** "Bevyxxa®: 30 capsules per 30 days" **under Quantity/Days Supply Restrictions**. 5. **Added** "Venous Thromboembolism (VTE) Prophylaxis: One time for a total of 42 days." **following Authorization under Approval Length**. 6. **Added** "Venous Thromboembolism (VTE) Prophylaxis: N/A" **following Re-Authorization under Approval Length**. 7. **Updated** "http://www.janssenmedicalinformation.com/assets/pdf/products/files/Xarelto/pi/ENC-010330-11.pdf" **to** "https://www.xarelto-us.com/shared/product/xarelto/prescribing-information.pdf" **under References**. 8. **Added** "http://www.bevyxxa.com/docs/Bevyxxa-Full-Prescribing-Information.pdf" **under References**.
9/23/2016	1. **Moved** "Xarelto® (rivaroxaban)" **from** "Non-Preferred" **to** "Preferred" **under Applicable Drugs**. 2. **Changed** "Savaysa™" **to** "Savaysa®" **throughout policy**. 3. **Changed** "III. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to the preferred product" **to** "III. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to the preferred product(s)" **under Prior Authorization Criteria**.
3/16/2015	1. **Added** "Savaysa™ (edoxaban)" **to Non-Preferred list under Applicable Drugs**. 2. **Added** "8337003020" **to GPI Code**.

	3. **Added** "Savaysa™ is not recommended in patients with moderate to severe mitral stenosis" **under Exclusion Criteria**. 4. **Added** "Savaysa™: 30 tablets per 30 days" **under Quantity/Days Supply Restrictions**. 5. **Added** "http://dsi.com/prescribing-information-portlet/getPIContent?productName=Savaysa&inline=true" **under References**.
3/13/2015	1. **Changed** "I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis: A. Nonvalvular atrial fibrillation and criterion 1 is met: 1. Patient is not a candidate for warfarin therapy (see under Other Criteria for requirements); B. DVT or PE Treatment and criterion 1 is met: 1. Patient is not a candidate for warfarin therapy (see under Other Criteria for requirements); C. Reduction in the Risk of Recurrence of DVT and of PE and criterion 1 is met: 1. Patient is not a candidate for warfarin therapy (see under Other Criteria for requirements); D. Hip or Knee Replacement Surgery Prophylaxis of DVT…III. Non-preferred products ({Pradaxa®, Xarelto®) require a documented trial and failure of, intolerance to, or contraindication to the preferred product (Eliquis®)" **to** "I. Documented diagnosis of one of the following conditions A through D: A. Nonvalvular atrial fibrillation; B. DVT or PE Treatment; C. Reduction in the Risk of Recurrence of DVT and of PE; D. Hip or Knee Replacement Surgery Prophylaxis of DVT…III. Non-preferred products require a documented trial and failure of, intolerance to, or contraindication to the preferred product" **under Prior Authorization Criteria**. 2. **Removed** "Patient must meet one of the following criteria a or b in order to not be a candidate for warfarin therapy: a. Failure to maintain goal INR while compliant with warfarin therapy (must provide documentation of the last 4 INR lab values within the previous 60 days); An allergy, intolerance, or contraindication to warfarin therapy" **under Other Criteria**. 3. **Changed** "Eliquis®: Quantities of up to 60 tablets per 30 days; Pradaxa®: Quantities of up to 60 tablets per 30 days; Xarelto®: Quantities of up to 30 tablets per 30 days (Exception: If being prescribed for DVT or PE treatment, 42 tablets may be authorized for the first 21 days of treatment, followed by 30 tablets per 30 days thereafter)." **to** "Eliquis®: 60 tablets per 30 days - If being prescribed for DVT or PE treatment, 28 tablets may be authorized for the first 7 days of treatment, followed by 60 tablets per 30 days thereafter; Pradaxa®: 60 capsules per 30 days; Xarelto®: 30 tablets per 30 days - If being prescribed for DVT or PE treatment, 42 tablets may be authorized for the first 21 days of treatment, followed by 30 tablets per 30 days thereafter." **under Quantity/Days Supply Restrictions**.
1/18/2014	1. **Adapted policy to new format.** 2. **Added GPI codes**. 3. **Labeled** "Eliquis® (apixaban)" as "Preferred" and "Pradaxa® (dabigatran), Xarelto® (rivaroxaban)" as "Non-preferred" **under Applicable Drugs**. 4. **Changed Prior Authorization Criteria from:** "Documented diagnosis of one of the Covered Uses listed below AND must meet criteria listed with applicable diagnosis: Nonvalvular atrial fibrillation AND patient is not a candidate for warfarin therapy (see under Other Criteria for requirements) AND patient's creatinine clearance is at least 15 mL/min; DVT or PE Treatment (Xarelto® only) AND patient is not a candidate for warfarin therapy (see under Other Criteria for requirements) AND patient's creatinine clearance is at least 30 mL/min; Reduction in the Risk of Recurrence of DVT and of PE (Xarelto® only) AND patient is not a candidate for warfarin therapy (see under Other Criteria for requirements) AND patient's creatinine clearance is at least 30 mL/min; Hip or Knee Replacement Surgery

	Prophylaxis of DVT (Xarelto® only) AND patient's creatinine clearance is at least 30 mL/min; Minimum age requirement: 18 years old" **to:** "Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis: A. Nonvalvular atrial fibrillation and criterion 1 is met: 1. Patient is not a candidate for warfarin therapy (see under Other Criteria for requirements); B. DVT or PE Treatment and criterion 1 is met: 1. Patient is not a candidate for warfarin therapy (see under Other Criteria for requirements); C. Reduction in the Risk of Recurrence of DVT and of PE and criterion 1 is met: 1. Patient is not a candidate for warfarin therapy (see under Other Criteria for requirements); D. Hip or Knee Replacement Surgery Prophylaxis of DVT; Minimum age requirement: 18 years old; Non-preferred products ({Pradaxa®, Xarelto®) require a documented trial and failure of, intolerance to, or contraindication to the preferred product (Eliquis®)". 5. **Added** "Active pathological bleeding; Prosthetic heart valves" **to Exclusion Criteria**. 6. **Changed Other Criteria from** "Patient must meet one of the following criteria in order to not be a candidate for warfarin therapy: a) Failure to maintain goal INR while compliant with warfarin therapy (must provide documentation of the last 4 INR lab values within the previous 60 days); OR b) An allergy, intolerance, or contraindication to warfarin therapy" **to** "Patient must meet one of the following criteria a or b in order to not be a candidate for warfarin therapy: a. Failure to maintain goal INR while compliant with warfarin therapy (must provide documentation of the last 4 INR lab values within the previous 60 days); b. An allergy, intolerance, or contraindication to warfarin therapy". 7. **Changed Quantity/Days Supply Restrictions from** "Eliquis®: 60 tablets per 30 days; Pradaxa®: 60 tablets per 30 days; Xarelto®: Up to 30 tablets per 30 days (Exception: If being prescribed for DVT or PE treatment, 42 tablets may be authorized for the first 21 days of treatment, followed by 30 tablets per 30 days thereafter)" **to** "Eliquis®: Quantities of up to 60 tablets per 30 days; Pradaxa®: Quantities of up to 60 tablets per 30 days; Xarelto®: Quantities of up to 30 tablets per 30 days (Exception: If being prescribed for DVT or PE treatment, 42 tablets may be authorized for the first 21 days of treatment, followed by 30 tablets per 30 days thereafter)". 8. **Changed Authorization under Approval Length from** "Hip Replacement Surgery Prophylaxis of DVT (Xarelto® only): One time for a total of 35 days; Knee Replacement Surgery Prophylaxis of DVT (Xarelto® only): One time for a total of 12 days; All other Covered Uses: 1 year." **to** "Hip Replacement Surgery Prophylaxis of DVT: One time for a total of 35 days; Knee Replacement Surgery Prophylaxis of DVT: One time for a total of 12 days; All other Covered Uses: 1 year". 9. **Changed Re-Authorization under Approval Length from** "Hip or Knee Replacement Surgery Prophylaxis of DVT (Xarelto® only): N/A; All other Covered Uses: Updated letter of medical necessity" **to** "Hip or Knee Replacement Surgery Prophylaxis of DVT: N/A; All other Covered Uses: An updated letter of medical necessity or progress notes to confirm that current medical necessity criteria are met and that the medication is effective". 10. **Updated references** to include Medi-Span.

to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.