



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy Makena™ (hydroxyprogesterone caproate)

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Policy Number: 314

BCBSA Reference Number: 4.01.16

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

| Standard Formulary | |
|--------------------|------------------|
| Drug | Formulary Status |
| Makena™ | PA Required |

Commercial Members

We cover Makena™ to reduce the risk of preterm births in women when **ALL** the following criteria are met:

- Current singleton pregnancy
- Prior history of spontaneous preterm birth before 37 weeks gestation.

If above criteria are met, approval will be given for Makena™ for weekly administration between 16 and 36 weeks of gestation.

We do not cover the above drugs for other conditions not listed above.

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for Makena™ at one of the providers in our retail specialty pharmacy network, as listed below:

| Retail Specialty Pharmacy Contact Information: | |
|---|---|
| AcariaHealth Phone: 1-866-892-1202 Fax: 1-866-892-3223 Website: www.acariahealth.com | Caremark, Inc. Phone: 1-866-846-3096 Fax: 1-800-323-2445 Website: www.caremark.com |
| Accredo Health Group Phone: 1-877-988-0058 Fax: 1-866-489-1907 Website: www.accredo.com | |

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Instructions

- Prior authorization is required for all out patient sites of service
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
Pharmacy Operations: (800) 366-7778
- For all outpatient sites of service, physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- For all outpatient sites of service, physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

PPO and Indemnity Authorization Instructions

- Prior authorization **is** required when these medications are processed under the retail pharmacy benefit and home infusion therapy benefit.
- Prior authorization **is not** required when these drugs are purchased by the physician and administered in the office in accordance with this medical policy.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
Pharmacy Operations: (800) 366-7778

- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

HCPCS Codes

| HCPCS codes: | Code Description |
|--------------|--|
| J1725 | Injection, hydroxyprogesterone caproate, 1 mg [Makena] |

ICD-9-CM Diagnosis Codes

| ICD-9-CM diagnosis codes: | Code Description |
|---------------------------|---|
| V13.21 | Personal history of pre-term labor |
| V23.41 | Supervision of High-Risk Pregnancy with history of pre-term labor |

ICD-10 Diagnosis Codes

| ICD-10-CM Diagnosis codes: | Code Description |
|----------------------------|--|
| Z87.51 | Personal history of pre-term labor |
| O09.212 | Supervision of pregnancy with history of pre-term labor, second trimester |
| O09.213 | Supervision of pregnancy with history of pre-term labor, third trimester |
| O09.219 | Supervision of pregnancy with history of pre-term labor, unspecified trimester |

Policy History

| Date | Action |
|----------------|--|
| 7/2014 | Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015. |
| 2/2014 | Removal of Curascript from Specialty Pharmacy section. |
| 1/2014 | Updated ExpressPAtH Language and removed Blue Value. |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements. |
| 4/2012 | Updated 4/2012 with specialty pharmacy contact information. |
| 1/2012 | Updated to include MED UM requirements for HMO and POS products, remove Walgreens specialty pharmacy information, and include revised HCPCS Level II code. |
| 9/2011 | Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. |

| | |
|----------|---|
| | No changes to policy statements. |
| 9/1/2011 | New Policy, effective 9/1/2011, describing covered and non-covered indications. |

References

1. Makena™ injection [package insert]. St. Louis, MO: Ther - Rx Corporation; January, 2011.
2. Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. N Engl J Med. 2003; 348:2379-2385.
3. U.S. Food and Drug Administration. FDA approves drug to reduce risk of preterm birth in at-risk pregnant women. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242234.htm>. Accessed July 7, 2011.
4. U.S. Food and Drug Administration. FDA Statement on Makena. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm>. Last accessed July 7, 2011.
5. Rode L, Langhoff-Roos J, Anderson C et al. Systematic review of progesterone for the prevention of preterm birth in singleton pregnancies. Acta Obstet Gynecol 2009; 88(11):1180-9.

Request for Outpatient Retail Pharmacy Prior Authorization

Fax to: Clinical Pharmacy Program (800) 583-6289

Phone Authorization (800)366-7778 or Web: <https://provider.express-path.com>

We plan to respond to your request within two business days of our receipt. To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

| | |
|---|-----------------------------|
| We cannot process requests unless they contain all of the information requested below: | |
| Patient Information (REQUIRED) | |
| Name | |
| BCBSMA ID Number | |
| Is the patient a BCBSMA employee? If yes, please fax request to: (617) 246-4013 | Yes No |
| Date of Birth | |
| Patient's Diagnosis or ICD-9-CM code | |
| Physician Information (REQUIRED) | |
| Name | |
| Medical Specialty | |
| BCBSMA Provider number/NPI number | |
| Telephone Number | |
| Fax Number | |
| Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) | Yes No |
| Contact Name (if different from physician) | |
| Please select one of the three following sections to complete, depending on the nature of your request for the above-named patient. | |
| Formulary Exception Request | |
| Name of non-covered drug you want to prescribe | |
| Reason for Individual Consideration Request (please check one): <input type="checkbox"/> Treatment failure with the following covered drugs in class: <input type="checkbox"/> Documented adverse reaction to the following covered drugs: <input type="checkbox"/> Other clinical reason (please specify) _____ | |
| Quality Care Dosing Override Request | |
| Drug name, strength and quantity requested: | |
| Clinical reason for override (please specify) | |
| Outpatient Retail Pharmacy Prior Authorization Request | |
| Drug name: | |
| Start/End date (must be one year or less): | |
| Associated Co-morbid diagnosis: | |
| MD Signature: | Date: |



Outpatient Medical Prior Authorization Form
Please complete and fax to: (888) 641-5355
Please contact Pharmacy Operations with questions at (800) 366-7778
 If the patient is a BCBSMA employee, please fax the form to: (617) 246-4013

| | | | |
|---------------------------|------------------------------|----------------------------|------------------------------|
| Servicing Provider | Name: NPI Number: | Requesting Provider | Name: NPI Number: |
| Phone# | | Phone# | |
| Fax# | | Fax# | |
| Contact Person: | | Contact Person: | |
| Patient Name: | | DOB ___/___/___ | Diagnosis: |
| Patient BCBSMA ID# | | | |

Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) Yes No

Drug/Therapy:

Drug Name: _____

Dates of Service: ___/___/___ to ___/___/___

Dose: _____

Frequency: _____

| |
|--|
| Additional Clinical (including previous treatment failure): |
| |

Physician signature: _____

Date: _____