

Affected Programs: BadgerCare Plus Standard Plan, BadgerCare Plus Benchmark Plan, BadgerCare Plus Core Plan, Medicaid, SeniorCare

To: Federally Qualified Health Centers, Hospital Providers, Nurse Practitioners, Pharmacies, Physician Assistants, Physician Clinics, Physicians, Rural Health Clinics, HMOs and Other Managed Care Programs

Policy for Onabotulinumtoxin A (Botox®)

This *ForwardHealth Update* defines policy for Botox® effective for dates of service on and after March 1, 2013.

This *ForwardHealth Update* defines policy for Botox® effective for dates of service (DOS) on and after March 1, 2013.

Information included in this *Update* addresses the following:

- Coverage of Botox® to treat *chronic* migraines.
- Coverage of Botox® to treat urinary incontinence.
- Coverage of Botox® to treat other diagnoses.
- Discontinuation of reimbursement for Botox® billed with a National Drug Code (NDC) on a compound or noncompound claim.

Botox® is a neurotoxin used to treat a number of diagnoses including (but not limited to) cervical dystonia, limb spasticity, strabismus, chronic migraines, and urinary incontinence.

Botox® is covered for BadgerCare Plus Standard Plan, BadgerCare Plus Benchmark Plan, BadgerCare Plus Core Plan, and Medicaid members. It is *not* covered for BadgerCare Plus Basic Plan or SeniorCare members.

For members enrolled in BadgerCare Plus HMOs, Medicaid SSI HMOs, and most special managed care programs, claims for Botox® should be submitted to BadgerCare Plus and Medicaid fee-for-service for reimbursement.

Coverage of Botox® to Treat Chronic Migraines

Effective for DOS on and after March 1, 2013, Botox® for use to treat *chronic* migraines will require prior authorization (PA) requested by the administering neurologist on a new form, the Prior Authorization Drug Attachment for Onabotulinumtoxin A (Botox®) to Treat Chronic Migraines, F-00701 (03/13). Copies of the new form and instructions are included in Attachments 1 and 2 of this *Update*.

The new form will be effective for DOS on and after March 1, 2013. Claims for Botox® to treat chronic migraines will be denied if an approved PA request is not on file for the member.

Submitting Prior Authorization Requests for Botox® to Treat Chronic Migraines

Prior authorization requests for Botox® to treat chronic migraines must be submitted by the neurologist who will be administering the Botox® treatment to the member.

To request PA for Botox® to treat chronic migraines, the neurologist is required to submit the following:

- A completed Prior Authorization Request Form (PA/RF), F-11018 (07/12).
- A completed Prior Authorization Drug Attachment for Onabotulinumtoxin A (Botox®) to Treat Chronic Migraines.

A copy of the PA/RF can be found on the Forms page of the ForwardHealth Portal.

Prior authorization requests for Botox® to treat chronic migraines may be submitted on the Portal, by fax, or by mail.

Note: The Portal submission option will not be available until March 8, 2013.

For detailed information about these submission options, refer to the Prior Authorization section of the Physician service area of the Online Handbook on the Portal at www.forwardhealth.wi.gov/.

Initial Prior Authorization Approval Criteria for Botox® to Treat Chronic Migraines

Clinical criteria for approval of an initial PA request for Botox® to treat chronic migraines are the following:

- The member is 18 years of age or older.
- The service is ordered by a neurologist who has evaluated the member and diagnosed the member as experiencing chronic migraines using the revised International Headache Society criteria for chronic migraines, which can be found on the following Web site: ibs-classification.org/en/02_klassifikation/05_anhang/01.05.01_anhang.html.

Note: The requesting neurologist is required to be the administering provider of the Botox® treatment to the member.

- The member has experienced headaches (tension-type and/or migraine) for **three or more** months that have lasted **four or more** hours per day on **15 or more** days per month, with **eight or more** headache days per month being migraines/probable migraines (and that are not due to medication overuse or attributed to another causative disorder).
- The member scored a grade indicating moderate to severe disability on the Migraine Disability Assessment (MIDAS) test, or on a similar validated tool. The

MIDAS test was developed by the American Headache Society for Headache Education and can be accessed at the following Web address: www.achenet.org/midas/.

- The neurologist has discussed alternative non-pharmacological treatment options with the member, such as behavioral therapies, physical therapies, and lifestyle modifications.
- **One** of the following is true:
 - ✓ The member has tried migraine prophylaxis medications from **three or more** of the drug categories listed below and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction:
 - Antidepressants.
 - Anticonvulsants.
 - Beta blockers.
 - Calcium channel blockers.
 - Other drugs.
 - ✓ The member has a medical condition that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed above, or there is a clinically significant drug interaction with a medication the member is currently taking that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed above.

If an initial PA request for Botox® to treat chronic migraines is approved, it will be approved for no more than two treatments in six months.

First Renewal Prior Authorization Approval Criterion for Botox® to Treat Chronic Migraines

The clinical criterion for approval of a first renewal PA request for Botox® to treat chronic migraines is that the member has experienced clinically significant and documented improvement in the frequency or duration of chronic migraines using at least **one** of the following indicators:

- Reduction in acute services, emergency services, or need for rescue treatment for acute chronic migraines.

- At least a 40 percent reduction in the frequency, severity, or length of chronic migraines.
- Improved assessment score on MIDAS test or on a similar validated tool.
- Reduced use of analgesics.

If a first renewal PA request for Botox® to treat chronic migraines is approved, it may be approved for up to two additional treatments in a six-month period.

Subsequent Renewal Prior Authorization Approval Criterion for Botox® to Treat Chronic Migraines

The clinical criterion for approval of a subsequent renewal PA request for Botox® to treat chronic migraines is that the member **continues to experience** the previously documented clinically significant improvement in the frequency or duration of chronic migraines as a result of Botox® treatment.

If a subsequent renewal PA request for Botox® to treat chronic migraines is approved, it may be approved for up to four additional treatments in a 12-month period.

Note: Members who have previously received Botox® treatments for chronic migraines are required to meet the new approval criteria in order for claims for the Botox® treatments to be reimbursed. Prior authorization requests for Botox® to treat chronic migraines that have already been approved will be honored until the expiration date.

Coverage of Botox® to Treat Urinary Incontinence

Effective for DOS on and after March 1, 2013, Botox® used to treat urinary incontinence in an outpatient hospital setting (and *only* in an outpatient hospital setting) will *not* require PA.

If it is clinically appropriate to administer Botox® to treat urinary incontinence anywhere other than in an outpatient hospital setting, a PA request must be submitted.

The following must be submitted to request PA for Botox® to treat urinary incontinence:

- A completed PA/RF.
- A completed Prior Authorization/”J” Code Attachment (PA/JCA), F-11034 (07/12).
- Documentation of why it is clinically appropriate for the member to receive the treatment in a setting other than an outpatient hospital.

Copies of the PA/RF and PA/JCA can be found on the Forms page of the Portal.

Prior authorization requests for Botox® to treat urinary incontinence may be submitted on the Portal, by fax, or by mail.

Note: The Portal submission option will not be available until March 8, 2013.

For detailed information about these submission options, refer to the Prior Authorization section of the Physician service area of the Online Handbook on the Portal.

Coverage of Botox® to Treat Other Diagnoses

For uses other than the treatment of chronic migraines or urinary incontinence, Botox® is a diagnosis-restricted drug. Botox® is covered without PA for any of the diagnoses listed on the Diagnosis Code-Restricted Physician-Administered Drugs data table on the Physicians page of the Portal. The table lists ForwardHealth-approved diagnoses with their corresponding *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnosis codes. Claims for Botox® not for use to treat chronic migraines or urinary incontinence are only reimbursable without PA when submitted with one of the approved ICD-9-CM diagnosis codes.

ForwardHealth has revised the Diagnosis Code-Restricted Physician-Administered Drugs data table to reflect all of the allowed diagnoses for Botox® that do not require PA. Diagnosis codes not listed on the table require PA.

Note: Diagnosis restrictions only apply to professional claims.

Submitting Prior Authorization Requests for Botox® to Treat Other Diagnoses

When PA is required, the following forms must be submitted to request PA for Botox® to treat diagnoses other than chronic migraines:

- A completed PA/RF.
- A completed PA/JCA.

Copies of the PA/RF and PA/JCA can be found on the Forms page of the Portal.

Like PA requests for Botox® to treat chronic migraines or urinary incontinence, PA requests for Botox® to treat diagnoses not listed on the Diagnosis Code-Restricted Physician-Administered Drugs data table may be submitted on the Portal, by fax, or by mail.

Note: The Portal submission option will not be available until March 8, 2013.

For detailed information about these submission options, refer to the Prior Authorization section of the Physician service area of the Online Handbook on the Portal. In addition to the PA request forms, providers are required to submit peer-reviewed medical literature to support the proven efficacy of the requested use of Botox®.

Claims Submission for Botox®

Compound and Noncompound Drug Claims No Longer Reimbursed

Effective for DOS on and after March 1, 2013, ForwardHealth will no longer reimburse claims for Botox® that are submitted on a compound or noncompound drug claim with an NDC. Claims for Botox® will only be reimbursed when submitted on a professional or institutional claim. Claims for Botox® that are submitted on a compound or noncompound drug claim will be denied.

Professional Claims for Botox®

Professional claims for Botox® should be submitted according to the current claims submission requirements for provider-administered drugs (including the requirements for compliance with the Deficit Reduction Act of 2005). Refer to the Claims section of the Physician service area of the Online Handbook for detailed information about these requirements.

Example of How to Determine Number of Units for Billing

The following is an example of how the number of units would be determined when billing Botox® on a professional claim.

Note: This is an example only. Providers are required to determine the appropriate codes/units to bill based on the specific details of the treatment administered. Providers should note that 100-unit and 200-unit vials of Botox® have different NDCs. In all cases, the provider should bill in the manner that produces the least amount of waste.

Example

A member received the standard treatment dose of Botox® for chronic migraines, which is 155 units.

Since Botox® comes in 100-unit and 200-unit single-use vials, the neurologist could have used either one 200-unit vial or two 100-unit vials. (ForwardHealth allows billing for waste in either case.) For this example, the neurologist used one 200-unit vial.

On the professional claim for this example, the number of units for the Healthcare Common Procedure Coding System (HCPCS) code and the NDC would be indicated as follows:

- For HCPCS code J0585 (Injection, onabotulinumtoxin, 1 unit), 200 units would be indicated (including the 45 units of waste).
- For NDC N400023392102 UN1, one unit would be indicated (representing the number of 200-unit vials used).

Institutional Claims for Botox® to Treat Urinary Incontinence

Claims for Botox® to treat urinary incontinence in an outpatient hospital setting must be submitted on an institutional claim using one of the following:

- The 837 Health Care Claim: Institutional transaction.
- Provider Electronic Solutions software.
- Direct Data Entry on the Portal.
- A UB-04 Claim Form.

Claims for Botox® to treat urinary incontinence anywhere other than in an outpatient hospital setting should be submitted according to the current claims submission requirements for provider-administered drugs.

Required Use of Most Specific Diagnosis Codes

As a reminder, all diagnosis codes indicated on claims (and PA requests when applicable) must be the most specific ICD-9-CM diagnosis code. Valid, most specific diagnosis codes may have up to five digits. Claims submitted with three- or four-digit codes where four- and five-digit codes are available may be denied.

Providers are responsible for keeping current with diagnosis code changes. Etiology and manifestation codes may not be used as a primary diagnosis.

Information Regarding Managed Care Organizations

This *Update* contains fee-for-service policy and applies to services members receive on a fee-for-service basis only. For managed care policy, contact the appropriate managed care organization. Managed care organizations are required to provide at least the same benefits as those provided under fee-for-service arrangements.

The *ForwardHealth Update* is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Health Care Access and Accountability, Wisconsin Department of Health Services (DHS). The Wisconsin AIDS/HIV Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, Wisconsin DHS.

For questions, call Provider Services at (800) 947-9627 or visit our Web site at www.forwardhealth.wi.gov/.

P-1250

ATTACHMENT 1

Prior Authorization Drug Attachment for Onabotulinumtoxin A (Botox[®]) to Treat Chronic Migraines Completion Instructions

(A copy of the “Prior Authorization Drug Attachment for Onabotulinumtoxin A [Botox[®]] to Treat Chronic Migraines Completion Instructions” is located on the following pages.)

FORWARDHEALTH PRIOR AUTHORIZATION DRUG ATTACHMENT FOR ONABOTULINUMTOXIN A (BOTOX®) TO TREAT CHRONIC MIGRAINES COMPLETION INSTRUCTIONS

ForwardHealth requires certain information to enable the programs to authorize and pay for medical services provided to eligible members.

Members of ForwardHealth are required to give providers full, correct, and truthful information for the submission of correct and complete claims for reimbursement. This information should include, but is not limited to, information concerning enrollment status, accurate name, address, and member identification number (DHS 104.02[4], Wis. Admin. Code).

Under s. 49.45(4), Wis. Stats., personally identifiable information about program applicants and members is confidential and is used for purposes directly related to ForwardHealth administration such as determining eligibility of the applicant, processing prior authorization (PA) requests, or processing provider claims for reimbursement. Failure to supply the information requested by the form may result in denial of PA or payment for the services. Providers are expected to be able to make available upon request clinical documentation supporting all information submitted on this form.

Neurologists are required to use this form when requesting PA for Onabotulinumtoxin A (Botox®) to treat chronic migraines. If necessary, attach additional pages if more space is needed. Refer to the applicable service-specific publications for service restrictions and additional documentation requirements. Provide enough information for ForwardHealth to make a determination about the request.

Neurologists may submit PA requests on the Prior Authorization Drug Attachment for Onabotulinumtoxin A (Botox®) to Treat Chronic Migraines form, F-00701, in one of the following ways:

- 1) For requests submitted on the ForwardHealth Portal, neurologists can access www.forwardhealth.wi.gov/.
- 2) For requests submitted by fax, neurologists should submit a Prior Authorization Request Form (PA/RF), F-11018, and the PA drug attachment form to ForwardHealth at (608) 221-8616.
- 3) For requests submitted by mail, neurologists should send a PA/RF and the PA drug attachment form to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

Neurologists should make duplicate copies of all paper documents mailed to ForwardHealth. The provision of services that are greater than or significantly different from those authorized may result in nonpayment of the billing claim(s).

SECTION I — MEMBER AND PROVIDER INFORMATION

Element 1 — Name — Member

Enter the member's last name, first name, and middle initial. Use Wisconsin's Enrollment Verification System (EVS) to obtain the correct spelling of the member's name. If the name or spelling of the name on the ForwardHealth identification card and the EVS do not match, use the spelling from the EVS.

Element 2 — Member Identification Number

Enter the member ID. Do not enter any other numbers or letters.

Element 3 — Date of Birth — Member

Enter the member's date of birth in MM/DD/CCYY format.

Element 4 — Name — Neurologist

Enter the name of the neurologist ordering the service for which PA is being requested.

Element 5 — National Provider Identifier (NPI) — Neurologist

Enter the neurologist's 10-digit National Provider Identifier (NPI).

Element 6 — Address — Neurologist

Enter the address (street, city, state, and ZIP+4 code) of the neurologist.

Element 7 — Telephone Number — Neurologist

Enter the telephone number, including area code, of the neurologist.

Element 8 — Name — Billing Provider

Enter the name of the billing provider.

Element 9 — NPI — Billing Provider

Enter the billing provider's NPI.

SECTION II — DRUG ORDER INFORMATION

If this section is completed, neurologists do not need to include a copy of the drug order for Botox®.

Element 10 — Drug Name

This element is populated with Onabotulinumtoxin A (Botox®).

Element 11 — HCPCS Drug Code

This element is populated with J0585.

Element 12 — Treatment Dose (In Units)

Enter the number of units of Botox® that will be administered per treatment.

Element 13 — Frequency of Treatments

Enter the frequency with which the member will receive Botox® treatments.

Element 14 — Units to Be Billed Per Treatment

Enter the number of units of Botox® that will be billed per treatment (the units administered plus the units wasted). Botox® comes in 100-unit and 200-unit single-use vials.

SECTIONS III, IV, or V

Neurologists are required to complete *one* of Section III, IV, or V.

SECTION III — CLINICAL INFORMATION FOR BOTOX® — INITIAL REQUESTS ONLY

Element 15

Indicate whether or not the member is 18 years of age or older.

Element 16

Indicate whether or not the neurologist has evaluated the member and diagnosed the member as experiencing chronic migraines using the Revised International Headache Society criteria for chronic migraines.

Element 17

Indicate whether or not the member has experienced headaches (tension-type and/or migraine) for **three or more** months that have lasted **four or more** hours per day on **15 or more** days per month, with **eight or more** headache days per month being migraines/probable migraines (and that are not due to medication overuse or attributed to another causative disorder).

Element 18

Indicate whether or not the member scored a grade indicating moderate to severe disability on the Migraine Disability Assessment (MIDAS) test or on a similar validated tool.

Element 19

Indicate whether or not the neurologist has discussed alternative nonpharmacological treatment options with the member, such as behavioral therapies, physical therapies, and lifestyle modifications.

Element 20

Check the boxes next to the drug categories from which the member has tried migraine prophylaxis medications. In the space provided, document the names of the medications tried, the approximate dates the medications were received, and specific details about the treatment results, including if the medications resulted in an unsatisfactory therapeutic response or a clinically significant adverse drug reaction.

Indicate whether or not the member has tried migraine prophylaxis medications from **three or more** of the drug categories listed. If “no,” indicate whether or not the member has a medical condition that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed, or indicate whether or not there is a clinically significant drug interaction with a medication the member is currently taking that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed. Document specific details about the member’s medical condition or the clinically significant drug interaction in the space provided.

SECTION IV — CLINICAL INFORMATION FOR BOTOX® — FIRST RENEWAL REQUEST ONLY (Following Initial Approval Only)

Complete this section for first renewal requests for Botox®, following approval of an initial PA request for Botox®.

Element 21

Indicate whether or not the member has experienced clinically significant and documented improvement in the frequency or duration of chronic migraines using at least **one** of the indicators listed. If “yes,” check all of the indicators that apply. If “no,” explain the medical necessity for further treatment.

SECTION V — CLINICAL INFORMATION FOR BOTOX® — SUBSEQUENT RENEWAL REQUEST ONLY (Following First Renewal Approval Only)

Complete this section for subsequent renewal requests for Botox®, following approval of a first renewal PA request for Botox®.

Element 22

Indicate whether or not the member continues **to experience** the previously documented clinically significant improvement in the frequency or duration of chronic migraines as a result of Botox® treatment. If “no,” explain the medical necessity for further treatment.

SECTION VI — ATTESTATION AND AUTHORIZED SIGNATURE

Element 23 — Signature — Neurologist

The neurologist is required to complete and sign this form.

Element 24 — Date Signed — Neurologist

Enter the month, day, and year the form was signed by the neurologist in MM/DD/CCYY format.

SECTION VII — ADDITIONAL INFORMATION

Element 25

Indicate any additional information in the space provided. Additional diagnostic and clinical information explaining the need for the product requested may be included here.

ATTACHMENT 2
Prior Authorization Drug Attachment for
Onabotulinumtoxin A (Botox®) to
Treat Chronic Migraines

(A copy of the “Prior Authorization Drug Attachment for Onabotulinumtoxin A [Botox®] to Treat Chronic Migraines” form is located on the following pages.)

FORWARDHEALTH
PRIOR AUTHORIZATION DRUG ATTACHMENT FOR ONABOTULINUMTOXIN A (BOTOX®)
TO TREAT CHRONIC MIGRAINES

Instructions: Type or print clearly. Before completing this form, refer to the Prior Authorization Drug Attachment for Onabotulinumtoxin A (Botox®) to Treat Chronic Migraines Completion Instructions, F-00701A.

SECTION I — MEMBER AND PROVIDER INFORMATION

1. Name — Member (Last, First, Middle Initial)

2. Member Identification Number

3. Date of Birth — Member

4. Name — Neurologist

5. National Provider Identifier (NPI) — Neurologist

6. Address — Neurologist (Street, City, State, ZIP+4 Code)

7. Telephone Number — Neurologist

8. Name — Billing Provider

9. NPI — Billing Provider

SECTION II — DRUG ORDER INFORMATION

10. Drug Name

Onabotulinumtoxin A (Botox®)

11. HCPCS Drug Code

J0585

12. Treatment Dose (In Units)

13. Frequency of Treatments

14. Units to Be Billed Per Treatment

SECTION III — CLINICAL INFORMATION FOR BOTOX® — INITIAL REQUEST ONLY

15. Is the member 18 years of age or older?

Yes No

16. Has the neurologist evaluated the member and diagnosed the member as experiencing chronic migraines using the Revised International Headache Society criteria for chronic migraines?

Yes No

17. Has the member experienced headaches (tension-type and/or migraine) for **three or more** months that have lasted **four or more** hours per day on **15 or more** days per month, with **eight or more** headache days per month being migraines / probable migraines (and that are not due to medication overuse or attributed to another causative disorder)?

Yes No

18. Did the member score a grade indicating moderate to severe disability on the Migraine Disability Assessment (MIDAS) test or on a similar validated tool?

Yes No

19. Has the neurologist discussed alternative nonpharmacological treatment options with the member, such as behavioral therapies, physical therapies, and lifestyle modifications?

Yes No

Continued



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SECTION III — CLINICAL INFORMATION FOR BOTOX® — INITIAL REQUEST ONLY (Continued)

20. Check the boxes next to the drug categories from which the member has tried migraine prophylaxis medications. In the space provided, document the following:

- The names of the medications tried.
- The approximate dates the medications were received.
- Specific details about the treatment results, including if the medications resulted in an unsatisfactory therapeutic response or a clinically significant adverse drug reaction.

1. Antidepressants _____

2. Anticonvulsants _____

3. Beta blockers _____

4. Calcium channel blockers _____

5. Other drugs _____

Has the member tried migraine prophylaxis medications from **three or more** of the drug categories listed above?

Yes No

If not, does the member have a medical condition that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed above, or is there a clinically significant drug interaction with a medication the member is currently taking that prevents him or her from trying migraine prophylaxis medications from **three or more** of the drug categories listed above?

Yes No

Document specific details about the member's medical condition or the clinically significant drug interaction.

SECTION IV — CLINICAL INFORMATION FOR BOTOX® — FIRST RENEWAL REQUEST ONLY (Following Initial Approval Only)

21. Has the member experienced clinically significant and documented improvement in the frequency or duration of chronic migraines using at least **one** of the indicators below? Yes No

If yes, check all that apply.

- Reduction in acute services, emergency services, or need for rescue treatment for acute chronic migraines.
- At least a 40 percent reduction in the frequency, severity, or length of chronic migraines.
- Improved assessment score on MIDAS test, or on similar validated tool.
- Reduced use of analgesics.

If no, explain the medical necessity for further treatment.

SECTION V — CLINICAL INFORMATION FOR BOTOX® — SUBSEQUENT RENEWAL REQUESTS ONLY (Following First Renewal Approval Only)

22. Does the member **continue to experience** the previously documented clinically significant improvement in the frequency or duration of chronic migraines as a result of Botox® treatment? Yes No

If no, explain the medical necessity for further treatment.

SECTION VI — ATTESTATION AND AUTHORIZED SIGNATURE

23. SIGNATURE — Neurologist

24. Date Signed — Neurologist

SECTION VII — ADDITIONAL INFORMATION

25. Include any additional information in the space below. Additional diagnostic and clinical information explaining the need for the product requested may be included here.