



Update

October 2012

No. 2012-54

Affected Programs: BadgerCare Plus, Medicaid

To: Nurse Practitioners, Physician Assistants, Physician Clinics, Physicians, HMOs and Other Managed Care Programs

Prior Authorization Policy for Lumizyme and Myozyme

Effective for dates of service on and after November 1, 2012, Lumizyme and Myozyme will require prior authorization.

Coverage of Lumizyme and Myozyme

Effective for dates of service (DOS) on and after November 1, 2012, prior authorization (PA) will be required for Lumizyme and Myozyme. Prescribers, *not* pharmacy providers, are required to submit PA requests for Lumizyme and Myozyme.

Lumizyme and Myozyme are covered for BadgerCare Plus Standard Plan, BadgerCare Plus Benchmark Plan, BadgerCare Plus Core Plan, and Medicaid members.

Lumizyme and Myozyme are 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 Lumizyme and Myozyme should be submitted to BadgerCare Plus and Medicaid on a fee-for-service basis.

Lumizyme is only available to be dispensed under a manufacturer's restricted distribution program. Providers are required to comply with the manufacturer's guidelines. For more information regarding these guidelines, providers should contact the manufacturer.

Initial Prior Authorization Approval Criteria for Lumizyme

The clinical criteria for approval of an initial PA request for Lumizyme are *all* of the following:

- The member has a diagnosis of late-onset (non-infantile) Pompe disease.
- The member's diagnosis of late-onset Pompe disease is based on *both* of the following:
 - ✓ Acid alpha-glucosidase (GAA) enzyme assay that shows reduced enzyme activity at less than 40 percent of the lab-specific normal mean value.
 - ✓ Confirmation by a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblast, or muscle) or by GAA gene sequencing.
- The member is 8 years of age or older.
- The member has a forced vital capacity (FVC) 30 percent to 79 percent of predicted value while in the sitting position.
- The member has a postural drop in FVC (in liters) of 10 percent or more from upright to supine position.
- The member has the ability to walk 40 meters on a six-minute walk test (assistive devices permitted).
- The member has muscle weakness in the lower extremities.

Documentation that the member meets these criteria (including supporting medical records) should be submitted with the initial PA request.

Subsequent Prior Authorization Approval Criteria for Lumizyme

The clinical criteria for approval of a subsequent PA request for Lumizyme are *both* of the following:

- The member is ambulatory (assistive devices permitted).
- The member is not ventilator dependent.

Note: The prescriber should indicate the member's ambulation and ventilator status on the PA request.

Initial Prior Authorization Approval Criteria for Myozyme

The clinical criteria for approval of an initial PA request for Myozyme are *all* of the following:

- The member has a diagnosis of infantile-onset Pompe disease.
- The diagnosis of infantile-onset Pompe disease is based on *both* of the following:
 - ✓ Acid alpha-glucosidase enzyme assay from dried blood spot or mixed leukocytes.
 - ✓ Confirmation by at least one secondary test to support the diagnosis (e.g., GAA enzyme assay in culture of skin fibroblasts or muscle biopsy, deoxyribonucleic mutational analysis, or lymphocyte vacuolation on blood films).

Documentation that the member meets these criteria (including supporting medical records) should be submitted with the initial PA request.

Subsequent Prior Authorization Approval Criterion for Myozyme

The clinical criterion for approval of a subsequent PA request for Myozyme is that the member is not ventilator dependent.

Note: The prescriber should indicate the member's ventilator status on the PA request.

Submitting Prior Authorization Requests for Lumizyme and Myozyme

Prior authorization for Lumizyme and Myozyme must be requested by prescribers or their designees, *not* pharmacy providers. If a PA request is submitted by a pharmacy provider, it will be returned.

ForwardHealth will begin accepting PA requests for Lumizyme and Myozyme on October 15, 2012, for DOS on and after November 1, 2012.

The following forms must be submitted with a PA request for Lumizyme or Myozyme:

- A completed Prior Authorization Request form (PA/RF), F-11018 (07/12). For special instructions on completing the PA/RF for Lumizyme or Myozyme, refer to the Completing the Prior Authorization Request Form section of this *ForwardHealth Update*. Copies of the PA/RF and instructions are included in Attachments 1 and 2 of this *Update* for reference purposes. The form and instructions have not changed.
- A completed Prior Authorization/“J” Code Attachment (PA/JCA), F-11034 (07/12). For special instructions on completing the PA/JCA for Lumizyme or Myozyme, refer to the Completing the Prior Authorization/ “J” Code Attachment section of this *Update*. Copies of the PA/JCA form and instructions are included in Attachments 3 and 4 for reference purposes. The form and instructions have not changed.

Prior authorization requests for Lumizyme and Myozyme may be submitted on the ForwardHealth Portal or on paper by fax or mail. Prescribers may submit PA requests via the secure Provider area of the Portal, which includes the capability to upload additional required documentation. For instructions on uploading documentation, prescribers may refer to the ForwardHealth Provider Portal Prior Authorization User Guide on the Portal User Guides page of the Portal at www.forwardhealth.wi.gov/.

Prescribers may submit paper PA requests by fax to ForwardHealth at (608) 221-8616 or by mail to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

Completing the Prior Authorization Request Form

When completing the PA/RF for Lumizyme or Myozyme, prescribers are required to enter the total quantity requested in units (where one unit equals 10 milligrams) in Element 22 of the form.

Prior authorization requests for Lumizyme and Myozyme will be approved for up to 365 days.

Completing the Prior Authorization/"J" Code Attachment

When completing the PA/JCA for Lumizyme or Myozyme, prescribers are required to enter the following information for the elements indicated (all elements on the form must be completed unless otherwise specified):

- **Element 4 — Drug Name** — Enter Lumizyme or Myozyme.
- **Element 5 — Strength** — Enter 50 mg vial.
- **Element 6 — National Drug Code** — Enter the National Drug Code (NDC) from the package.
- **Element 7 — HCPCS "J" Code** — Enter Healthcare Common Procedure Coding System (HCPCS) procedure code J0221 (Injection, alglucosidase alfa, [lumizyme], 10mg) for Lumizyme; enter J0220 (Injection, alglucosidase alfa, not otherwise specified, 10 mg) for Myozyme.
- **Element 8 — Quantity Ordered** — Enter the dose per administration in units, where one unit equals 10 milligrams.
- **Element 9 — Date Order Issued** — Enter the date the order for the product was issued.

- **Element 10 — Daily Dose** — Enter the dose per administration in milligrams. Enter the frequency of administration.
- **Element 13 — "Brand Medically Necessary"** — Leave blank.
- **Element 14 — Diagnosis** — Enter the appropriate *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis code.
- **Element 15 — Changes to Previous Clinical Condition** — Enter a statement indicating that the member meets the ForwardHealth PA clinical criteria for Lumizyme or Myozyme, and include the member's ambulation and ventilator status to date (as appropriate for the service requested). For initial PA requests, reference attached documentation (attached documentation should be appropriate for the service requested).
- **Element 18 — Signature — Prescriber** — The prescriber is required to sign the PA/JCA. (By signing the form, the prescriber is attesting that all information is true, to the best of his or her knowledge.)

Prior Authorization Amendments

If a member's weight changes, resulting in a change in dose for Lumizyme or Myozyme, the prescriber is required to amend an approved PA request for the appropriate dose. Prior authorization requests may be amended by submitting a Prior Authorization Amendment Request, F-11042 (07/12), to ForwardHealth electronically on the Portal or on paper by fax or mail.

Prescribers are required to indicate the following on PA amendment requests for Lumizyme or Myozyme:

- The member's most recent weight.
- The date the member's weight was measured.
- The new Lumizyme or Myozyme dose calculation.

Note: Prescribers have 30 days from the date of administering a dose change to amend an approved PA request for Lumizyme or Myozyme.

Professional Claim Submission

Claims for Lumizyme and Myozyme must be submitted on a professional claim using the Portal, the 837 Health Care Claim: Professional transaction, or the 1500 Health Insurance Claim Form.

On each claim submission, prescribers are required to indicate the following:

- HCPCS procedure code J0221 for Lumizyme or J0220 for Myozyme.
- The dosage in number of 10 milligram units administered. Lumizyme and Myozyme only come in 50 milligram vials; therefore, one vial is equal to five units. Prescribers may submit claims for partially used vials of Lumizyme and Myozyme.
- The appropriate procedure code, which must match the procedure code that was approved on the PA request.

To comply with the requirements of the Deficit Reduction Act of 2005, the following must also be indicated on claims for Lumizyme and Myozyme:

- The NDC of the drug dispensed.
- The code qualifier ME (milligrams).
- The quantity of milligrams dispensed.

Note: Outpatient pharmacy claims billed with an NDC will be denied.

Example of How Units Are Determined for Billing

The following is an example (using Lumizyme) of how the number of units would be determined for billing:

- With Lumizyme dosed at 20 milligrams/kilogram, the dose for a member weighing 68 kilograms (150 pounds) is 1,360 milligrams (20 multiplied by 68).
- At 50 milligrams per vial, the number of vials required is 27.2 (1,360 divided by 50).
- 27.2 vials is rounded up to 28 vials (allowing prescribers to bill for waste).
- 28 vials (at 50 milligrams per vial) equals 1,400 milligrams.

- 1,400 milligrams (indicated in 10 milligram units) equals 140 units to be billed.

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 Well Woman Program is 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 Request Form (PA/RF)

Completion Instructions for Prescribers for Drugs

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 PA requests, or processing provider claims for reimbursement. The use of this form is mandatory to receive PA of certain procedures/services/items. Failure to supply the information requested by the form may result in denial of PA or payment for the service.

Providers should make duplicate copies of all paper documents mailed to ForwardHealth. Providers may submit PA requests, along with all applicable service-specific attachments, via the ForwardHealth Portal, by fax to ForwardHealth at (608) 221-8616, or by mail to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

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 — PROVIDER INFORMATION

Element 1 — HealthCheck "Other Services" and Wisconsin Chronic Disease Program (WCDP)

Leave the box next to HealthCheck "Other Services" blank. Enter an "X" in the box next to WCDP if the services requested on the PA/RF are for a WCDP member.

Element 2 — Process Type

Enter process type **117 — Physician Services**. The process type is a three-digit code used to identify a category of service requested. PA requests will be returned without adjudication if no process type is indicated.

Element 3 — Telephone Number — Billing Provider

Enter the telephone number, including the area code, of the office, clinic, facility, or place of business of the billing provider.

Note: Prescribers who are certified by Wisconsin Medicaid should indicate their telephone number as the billing provider on PA requests. Prescribers who are not certified by Wisconsin Medicaid should indicate the telephone number of the Wisconsin Medicaid-certified billing provider (e.g., clinic) with which they are affiliated on PA requests.

Element 4 — Name and Address — Billing Provider

Enter the name and complete address (street, city, state, and ZIP+4 code) of the billing provider. Providers are required to include both the ZIP code and four-digit extension for timely and accurate billing. The name listed in this element must correspond with the billing provider number listed in Element 5a.

Note: Prescribers who are certified by Wisconsin Medicaid should indicate their name and address as the billing provider on PA requests. Prescribers who are not certified by Wisconsin Medicaid should indicate the name and address of the Wisconsin Medicaid-certified billing provider (e.g., clinic) with which they are affiliated on PA requests.

Element 5a — Billing Provider Number

Enter the NPI of the billing provider. The NPI in this element must correspond with the provider name listed in Element 4.

Note: Prescribers who are certified by Wisconsin Medicaid should indicate their provider number as the billing provider on PA requests. Prescribers who are not certified by Wisconsin Medicaid should indicate the provider number of the Wisconsin Medicaid-certified billing provider (e.g., clinic) with which they are affiliated on PA requests.

Element 5b — Billing Provider Taxonomy Code

Enter the national 10-digit alphanumeric taxonomy code that corresponds to the NPI of the billing provider in Element 5a.

Note: Prescribers who are certified by Wisconsin Medicaid should indicate their taxonomy code as the billing provider on PA requests. Prescribers who are not certified by Wisconsin Medicaid should indicate the taxonomy code of the Wisconsin Medicaid-certified billing provider (e.g., clinic) with which they are affiliated on PA requests.

SECTION II — MEMBER INFORMATION

Element 6 — Member Identification Number

Enter the member ID. Do not enter any other numbers or letters. Use the ForwardHealth identification card or Wisconsin's EVS to obtain the correct number.

Element 7 — Date of Birth — Member

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

Element 8 — Address — Member

Enter the complete address of the member's place of residence, including the street, city, state, and ZIP code. If the member is a resident of a nursing home or other facility, include the name of the nursing home or facility.

Element 9 — Name — Member

Enter the member's last name, followed by his or her first name and middle initial. Use the EVS to obtain the correct spelling of the member's name. If the name or spelling of the name on the ForwardHealth card and the EVS do not match, use the spelling from the EVS.

Element 10 — Gender — Member

Enter an "X" in the appropriate box to specify male or female.

SECTION III — DIAGNOSIS / TREATMENT INFORMATION

Element 11 — Diagnosis — Primary Code and Description

Enter the appropriate ICD-9-CM diagnosis code and description most relevant to the service/procedure requested.

Element 12 — Start Date — SOI (not required)

Element 13 — First Date of Treatment — SOI (not required)

Element 14 — Diagnosis — Secondary Code and Description

Enter the appropriate secondary ICD-9-CM diagnosis code and description relevant to the service/procedure requested, if applicable.

Element 15 — Requested PA Start Date

Enter the requested start DOS in MM/DD/CCYY format.

Element 16 — Rendering Provider Number

Enter the prescriber's NPI, only if the NPI is different from the NPI of the billing provider listed in Element 5a.

Element 17 — Rendering Provider Taxonomy Code

Enter the national 10-digit alphanumeric taxonomy code that corresponds to the prescriber only if this code is different from the taxonomy code listed for the billing provider in Element 5b.

Element 18 — Procedure Code (not required)

Element 19 — Modifiers (not required)

Element 20 — POS

Enter the appropriate place of service code designating where the requested item would be provided/performed/dispensed.

Element 21 — Description of Service

Enter the drug name and dose for each item requested (e.g., drug name, milligrams, capsules).

Element 22 — QR

Enter the appropriate quantity (e.g., days' supply) requested for each item requested.

Element 23 — Charge (not required)

Element 24 — Total Charges (not required)

Element 25 — Signature — Requesting Provider

The original signature of the provider requesting this item must appear in this element.

Element 26 — Date Signed

Enter the month, day, and year the PA/RF was signed (in MM/DD/CCYY format).

ATTACHMENT 2

Prior Authorization Request Form (PA/RF)

(A copy of the “Prior Authorization Request Form [PA/RF]” is located on the following page.)

FORWARDHEALTH PRIOR AUTHORIZATION REQUEST FORM (PA/RF)

Providers may submit prior authorization (PA) requests by fax to ForwardHealth at (608) 221-8616 or by mail to: ForwardHealth, Prior Authorization, Suite 88, 313 Blettner Boulevard, Madison, WI 53784. **Instructions:** Type or print clearly. Before completing this form, read the service-specific Prior Authorization Request Form (PA/RF) Completion Instructions.

SECTION I — PROVIDER INFORMATION		
1. Check only if applicable <input type="checkbox"/> HealthCheck "Other Services" <input type="checkbox"/> Wisconsin Chronic Disease Program (WCDP)	2. Process Type	3. Telephone Number — Billing Provider
4. Name and Address — Billing Provider (Street, City, State, ZIP+4 Code)		5a. Billing Provider Number
		5b. Billing Provider Taxonomy Code

SECTION II — MEMBER INFORMATION		
6. Member Identification Number	7. Date of Birth — Member	8. Address — Member (Street, City, State, ZIP Code)
9. Name — Member (Last, First, Middle Initial)	10. Gender — Member <input type="checkbox"/> Male <input type="checkbox"/> Female	

SECTION III — DIAGNOSIS / TREATMENT INFORMATION										
11. Diagnosis — Primary Code and Description					12. Start Date — SOI			13. First Date of Treatment — SOI		
14. Diagnosis — Secondary Code and Description					15. Requested PA Start Date					
16. Rendering Provider Number	17. Rendering Provider Taxonomy Code	18. Service Code	19. Modifiers				20. POS	21. Description of Service	22. QR	23. Charge
			1	2	3	4				

<p>An approved authorization does not guarantee payment. Reimbursement is contingent upon enrollment of the member and provider at the time the service is provided and the completeness of the claim information. Payment will not be made for services initiated prior to approval or after the authorization expiration date. Reimbursement will be in accordance with ForwardHealth payment methodology and policy. If the member is enrolled in a BadgerCare Plus Managed Care Program at the time a prior authorized service is provided, ForwardHealth reimbursement will be allowed only if the service is not covered by the Managed Care Program.</p> 25. SIGNATURE — Requesting Provider	24. Total Charges
26. Date Signed	



ATTACHMENT 3

Prior Authorization/"J" Code Attachment (PA/JCA) Completion Instructions

(A copy of the "Prior Authorization/"J" Code Attachment [PA/JCA] Completion Instructions" is located on the following pages.)

FORWARDHEALTH PRIOR AUTHORIZATION / "J" CODE ATTACHMENT (PA/JCA) 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 service.

The use of this form is mandatory when requesting PA for certain procedures. 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 case.

Physicians use this form to request PA for injectable drug ("J") codes. Attach the completed Prior Authorization/"J" Code Attachment (PA/JCA), F-11034, to the Prior Authorization Request Form (PA/RF), F-11018, and send it to ForwardHealth. Providers should make duplicate copies of all paper documents mailed to ForwardHealth. Providers may submit PA requests by fax to ForwardHealth at (608) 221-8616 or by mail to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

The provision of services that are greater than or significantly different from those authorized may result in nonpayment of the billing claim(s). Providers should amend a PA request before it expires if services are significantly different from or greater than those services prior authorized.

SECTION I — MEMBER INFORMATION

Element 1 — Name — Member

Enter the member's last name, followed by his or her 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 — Date of Birth — Member

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

Element 3 — Member Identification Number

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

SECTION II — DRUG ORDER INFORMATION

Complete all of Section II.

SECTION III — CLINICAL INFORMATION

Element 14 — Diagnosis

List the member's condition the prescribed drug is intended to treat. Include the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnosis code and the expected length of need.

Element 15 — Changes to Previous Clinical Condition

If requesting a renewal or continuation of a previous PA approval, indicate any changes to the clinical condition, progress, or known results to-date.

Element 16 — Use

Any of the compendium standards may be used. If an intended use is not in the drug package insert, providers may want to check the United States Pharmacopeia Dispensing Information (USP-DI) for the most inclusive reference for diagnosis.

Drugs not listed in compendium standards may be covered by ForwardHealth; therefore, the PA/JCA must be submitted for processing and denied before the member is told a particular drug is not reimbursable by ForwardHealth.

Element 17 — Dose

Any of the compendium standards may be used. If a prescribed dosage is not in the drug package insert, you may want to check the USP-DI (the most inclusive reference for diagnosis).

Drugs not listed in compendium standards may be covered by ForwardHealth; therefore, the PA/JCA must be submitted for processing and denied before the member is told a particular drug is not covered by ForwardHealth.

Elements 18 and 19 — Signature — Prescriber and Date Signed

The prescriber is required to review the information, verifying that the information is accurate to the best of his or her knowledge, and sign the PA/JCA.

ATTACHMENT 4

Prior Authorization/"J" Code Attachment (PA/JCA)

(A copy of the "Prior Authorization/'J' Code Attachment [PA/JCA]" is located on the following pages.)

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**FORWARDHEALTH
PRIOR AUTHORIZATION / "J" CODE ATTACHMENT (PA/JCA)**

Providers may submit prior authorization (PA) requests with attachments to ForwardHealth by fax at (608) 221-8616 or by mail to ForwardHealth, Prior Authorization, Suite 88, 313 Blettner Boulevard, Madison, WI 53784. **Instructions:** Type or print clearly. Before completing this form, read the Prior Authorization/"J" Code Attachment (PA/JCA) Completion Instructions, F-11034A.

SECTION I — MEMBER INFORMATION

1. Name — Member (Last, First, Middle Initial)	2. Date of Birth — Member
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3. Member Identification Number

SECTION II — DRUG ORDER INFORMATION

4. Drug Name	5. Strength
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6. National Drug Code	7. HCPCS "J" Code
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8. Quantity Ordered	9. Date Order Issued	10. Daily Dose
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11. Name — Prescriber

12. National Provider Identifier	13. "Brand Medically Necessary" <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please indicate and describe the adverse reaction, allergic reaction, or actual therapeutic failure in the space provided.
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SECTION III — CLINICAL INFORMATION

14. Diagnosis

15. Changes to Previous Clinical Condition
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Continued



SECTION III — CLINICAL INFORMATION (Continued)

16. Use (Check One)

- Compendium standards, such as the United States Pharmacopeia Dispensing Information (USP-DI) or drug package insert, lists the intended use previously identified as an accepted or a [bracketed] indication.
- The intended use identified above is *not* listed in compendium standards. Peer-reviewed clinical literature is attached.

17. Dose (Check One)

- The daily dose and duration are within compendium standards of general prescribing or dosing limits for the indicated use.
- The daily dose and duration are not within compendium standards of general prescribing or dosing limits for the intended use. Attach peer-reviewed literature that indicates this dose is appropriate or document the medical necessity of this dosing difference.

18. **SIGNATURE** — Prescriber

19. Date Signed
