Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee

Department Guidelines for the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee

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1.1 Preferred Drug List (PDL) Overview

A Brief Overview

ForwardHealth makes recommendations to the Wisconsin Medicaid Pharmacy Prior Authorization (PA) Advisory Committee on whether certain PDL drugs should be preferred or non-preferred. These recommendations are based primarily on objective evaluations of a drug's relative safety, effectiveness of the drug, clinical outcomes, and the relative cost of the drug (to Wisconsin Medicaid) in comparison with other therapeutically interchangeable alternative agents in the same drug class.

New drugs are usually added to existing drug classes on the PDL as non-preferred drugs until their next scheduled class review by the Pharmacy PA Advisory Committee.

The PDL is not a drug formulary and is not a comprehensive list of covered drugs.

Most drugs and drug classes included on the PDL are covered by the BadgerCare Plus, Medicaid, and SeniorCare, but certain drugs may have restrictions (e.g., diagnosis, quantity limits, age limits). Prescribers are encouraged to write prescriptions for preferred drugs if medically appropriate. Non-preferred drugs may be covered with an approved PA request. Most preferred drugs do not require PA except in designated classes identified on the Preferred Drug List Quick Reference. Noncovered drugs (e.g., drugs used for hair loss or cosmetic purposes) are not reimbursed, even with PA.

For more information please refer to the pharmacy page of the ForwardHealth Portal at the following link:

https://www.forwardhealth.wi.gov/WIPortal/content/provider/medicaid/pharmacy/resources.htm.spage

Wisconsin Medicaid's Online Handbook is also available on the Portal at the following link:

https://www.forwardhealth.wi.gov/WIPortal/Subsystem/KW/Display.aspx

Prescriber Responsibilities for Prior Authorization for Drugs

Prescribers are encouraged to write prescriptions for preferred drugs. Prescribers are encouraged to prescribe **more than one** preferred drug before a non-preferred drug is prescribed.

Clinical Criteria for Non-preferred Drugs

Clinical criteria for approval of a PA request for a non-preferred drug are **at least one** of the following, unless drug class-specific clinical criteria have been established and published by ForwardHealth:

- The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with **at least one** of the preferred drugs from the same PDL drug class as the drug being requested.
- There is a clinically significant drug interaction between another drug the member is taking and **at least one** of the preferred drugs from the same PDL drug class as the drug being requested.
- The member has a medical condition(s) that prevents the use of **at least one** of the preferred drugs from the same PDL drug class as the drug being requested

Alternate Clinical Criteria for Non-preferred Drugs in Eligible Drug Classes Only

The following drug classes have alternate clinical criteria that may be considered if the member does not meet the clinical criteria for non-preferred drugs listed above:

- Alzheimer's agents drug class (excluding memantine products for members who are 17 years of age or younger).
- Anticonvulsants drug class.
- Antidepressants, other drug class.
- Antidepressants, SSRI drug class.
- Antiparkinson's agents drug class.
- Antipsychotics drug class.
- Pulmonary arterial hypertension drug class.

Alternate clinical criteria may be considered if a member does not meet the previously listed clinical criteria for non-preferred drugs. Alternative clinical criteria are **one** of the following:

- The member is new to ForwardHealth (i.e., the member has been granted eligibility for ForwardHealth within the past month) and has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.
- The member had an approved PA issued by ForwardHealth that recently expired for the non-preferred drug, and the member has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.

- The member was recently discharged from an inpatient stay in which the member was stabilized on the non-preferred drug being requested.

Note: Starting a member on a medication by using manufacturer-provided samples or manufacturer patient assistance programs will not be considered as previous medication history for PA review.

Completing a Prior Authorization Form

If a non-preferred drug or a preferred drug that requires clinical PA is medically necessary for a member, the prescriber is required to do the following:

- Complete the appropriate PA form for the drug.
- Send the PA form to the pharmacy where the prescription will be filled.
- Include accurate and complete answers and clinical information about the member's medical history on the PA form.
- Provide his or her handwritten signature and date on the form.

The PA form may be faxed or mailed to the pharmacy, or the member may carry the form with the prescription to the pharmacy. The pharmacy provider will use the completed PA form to submit a PA request to ForwardHealth. Prescribers should **not** submit the PA form to ForwardHealth.

Prescribers are required to retain a completed, signed, and dated copy of the PA form and any supporting documentation. Pharmacy providers may not reuse PA forms from previously approved PA requests for subsequent PA submissions.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, which is available on the Forms page of the Portal, or to the Additional Information section available on most PA forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

Pharmacy Provider Responsibilities for Prior Authorization for Drugs

Pharmacy providers should review the Preferred Drug List Quick Reference for the most current list of preferred and non-preferred drugs.

If a member presents a prescription for a non-preferred drug, the pharmacy provider is encouraged to contact the prescriber to discuss preferred drug options. The prescriber may choose to change the prescription to a preferred drug, if medically appropriate for the member, or the prescriber may complete the appropriate PA form.

Pharmacy providers are required to:

- Submit the PA request using the PA form received from the prescriber and using the PA request submission option most appropriate for the drug. Pharmacy providers may submit PA requests using the STAT-PA system (when applicable), on the Portal, by fax, or by mail.
- Retain a completed, signed, and dated copy of the PA form and any supporting documentation received from the prescriber.

Pharmacy providers may not reuse PA forms from previously approved PA requests for subsequent PA request submissions.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, which is available on the Forms page of the Portal, or to the Additional Information section available on most PA forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

1.2 Committee Organization and Operation

Legal Authority

The Department of Health Services Secretary, according to s. 49.45(49)(a),Wis.Stats, shall exercise his or her authority under s. 15.04 (1)(c) to create a prescription drug prior authorization committee to advise the department on issues related to prior authorization decisions made concerning prescription drugs on behalf of medical assistance recipients. The Secretary shall appoint as members at least all of the following:

1. Two physicians, as defined in s. 448.01 (5), who are currently in practice.
2. Two pharmacists, as defined in s. 450.01 (15).
3. One advocate for recipients of medical assistance who has sufficient medical background, as determined by the department, to evaluate a prescription drug's clinical effectiveness.

Name of the Committee

The name of the organization shall be the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee, serving the Wisconsin Medicaid, BadgerCare Plus, and SeniorCare programs, administered by the Wisconsin Department of Health Services.

Membership and Qualifications

1. To ensure the ability to maintain quorum, the committee is composed of both standing committee members and alternate committee members.

a. The standing membership shall consist of health care professionals with an unrestricted license to practice in the State of Wisconsin and at least one advocate who have sufficient medical background to evaluate a prescription drug's clinical effectiveness.
b. Advanced Nurse Practitioners and Physicians Assistants must possess full prescribing authority for all scheduled and non-scheduled medications to be eligible for committee membership.
c. The majority of the standing committee members should be actively involved in the treatment of, or provision of healthcare services to, Wisconsin Medicaid members.
d. A psychiatrist should be made available if possible, to serve as a Clinical Consultant to the Committee anytime a Mental Health drug class is reviewed.
e. In recommending drug PDL status, the Committee should be attentive to the content of and changes to pertinent guidelines and policies of professional organizations and standards setting bodies such as the American Society of Health System Pharmacists, the American Hospital Association, medical and nursing associations, governmental organizations and others, as appropriate.
f. Committee members shall not receive monetary compensation or any other thing of value from a company or other organization that has a financial interest in the outcome of matter being reviewed by the Committee.
g. Committee members shall maintain confidential any member or financial information discussed and provided for review. Confidential information may be used only for purposes directly related to the administration of the PDL program.
h. Committee members shall not participate in meetings with drug manufacturers to specifically discuss topics directly related to an upcoming Committee meeting. Committee members may meet with drug manufacturers as it relates to their work outside of the Committee. Drug manufacturers are given the opportunity to provide information regarding their products during the public comment section of each Committee meeting. Committee members may contact the Department if there are questions about specific interactions with drug manufacturers.

Appointment and Term

1. Members of the Committee shall be appointed by the Secretary of the Department or authorized designee.
2. The Committee Chair shall be the Director of the Division of Medicaid Services (DMS).
3. Appointments of committee members will ordinarily be made for a minimum term of two years. However, members may serve additional terms as determined by the Director or authorized designee.

Resignation and Removal

1. A member of the Committee may resign by written notice to the Committee Chair and the Department.

2. Any member of the Committee may be removed by the Department for good cause. Good cause shall include at least one of the following:

a. Nonattendance – Two (2) unexcused consecutive absences from scheduled meetings shall constitute a resignation.
b. Professional misconduct.
c. Conflict of Interest – Undisclosed or unresolved conflict of interest.
d. Failure to meet eligibility requirements for Committee appointment.

Meeting Facilitation

1. The Chair's designee shall facilitate the Committee meeting in the absence of the Chair.
2. Department staff will prepare the agenda for the Committee meeting in consultation with the Committee Chair.
3. Department staff will be responsible to oversee the preparation and posting of a final meeting summary in the permanent records of the Committee.
4. An agenda, supplementary clinical materials, minutes of the previous meeting, and written testimony submitted by pharmaceutical manufacturers, providers, and others, shall be reviewed by Department staff and submitted to Committee members before each meeting.

1.3 Committee Responsibilities

Responsibilities

The Wisconsin Medicaid Pharmacy Prior Authorization Committee has the following responsibilities:

1. To serve in an evaluation, education and advisory capacity to the Wisconsin Medicaid Program specific to the recommendation of preferred and non-preferred status of drugs within the PDL.
2. Prior to each meeting, review evidence-based clinical data provided by the Department.
3. To make recommendations to the Department for the drugs to be considered for preferred and non-preferred status in selected classes of drugs.

4. Provide recommendations that are based primarily on objective evaluations of a drug's relative safety, effectiveness, medical necessity, clinical outcomes and relative cost to the Wisconsin Medicaid program of the agents, in comparison with other therapeutically interchangeable alternative agents in the same class of drugs.

Recommendations of the Committee will be presented to the Secretary for adoption, modification or referral back to DMS for further action or review.

1.4 Meeting Guidelines

Conduct of Meetings

1. The Prior Authorization Advisory Committee meeting is subject to Wisconsin Open Meeting Law – s. 19.81, Wis. Stats.
2. The Committee will meet at least two times per year, or more often as deemed necessary by the Department.
3. A part of the committee meeting agenda may be intended for consideration in closed session pursuant to s. 19.85(1) (e), Wis. Stats., due to the confidential nature of manufacturer specific Supplemental Rebate Amounts
4. A final meeting summary is the only formal record of the activities of the Committee meetings.
5. A simple majority of the standing committee membership of the Committee will constitute a quorum. A quorum is the minimum number of committee members who must be present at a properly called meeting in order to conduct business in the name of the group. For example, if the committee consists of 10 standing members and 3 alternate members, quorum is a majority of the standing members, quorum is 6 members. However, the 6 members required to reach quorum, may be comprised of both standing and/or alternate committee members present.
6. Recommendations of the Committee may be taken by a simple majority of committee members present provided there is a quorum.
7. All business of the Committee, including recommendations to the Department, shall be transacted by motion or resolution in open meeting, which may be made by any member in attendance, including the Chair or designee, and shall require a second.
8. Voting on all motions and resolutions shall be conducted in open session.
9. Voting on all motions and resolutions shall be by voice vote unless a member asks that the roll be called and that the vote of each member be recorded.
10. The acts of the majority of the Committee members present at a meeting at which a quorum is present shall be the acts of the Committee.

Public Participation and Public Testimony

1. Meetings will be open to the public, and shall comply with the Wisconsin Open Meetings Law. Notice of meetings will also be published on the ForwardHealth Portal, at least 10 days prior to each meeting.
2. Speakers are required to submit a Public Testimony Registration form prior to the meeting. A copy of the form can be obtained at the following link: https://www.forwardhealth.wi.gov/WIPortal/content/provider/pac/index.htm.spage
3. Please email a completed Public Testimony Registration form to DHSWIPDL@Wisconsin.gov to reserve a time slot. Speaking requests will be accepted approximately 45 days prior to the meeting date.
4. Speakers must also complete the Wisconsin Medicaid Pharmacy Prior Authorization Committee Presenter/Witness Disclosure form. This form will be emailed to speakers with your approximate speaking time.
5. Speakers must submit their completed and signed Presenter/Witness Disclosure form to DHSWIPDL@Wisconsin.gov prior to being allowed to speak.
6. If a speaker with an assigned time slot is unable to testify, the speaker must email DHSWIPDL@Wisconsin.gov prior to the meeting. If they have asked someone to speak in their place, that person should be identified in the communication.
7. Manufacturers' or their representatives' testimony should include the following information:
    - Specific new information that has become available about the drug since the last review
    - Any head-to-head studies that have been completed and published in peer reviewed medical journals that demonstrate superiority of your product within the class.
8. Written testimony may be submitted for review and consideration by the Committee. Written testimony by an individual or group must disclose the writer's employment, and, if not an employee of a drug manufacturer or group, must also disclose whether or not the writer or group receives compensation, gratuities or grants from or has an affiliation with any drug manufacturer or related group. Individuals writing on their own behalf should designate their correspondence as such.
9. Written testimony should be no longer than three pages in length. All other types of submitted materials (e.g. package inserts, marketing materials and reports) will not be provided to committee members
10. Written testimony must be emailed to DHSWIPDL@Wisconsin.gov. Written testimony must be received no later than three (3) business days prior to the meeting, to ensure time for committee members to receive it. Such communication should not be sent directly to any member of the Prior Authorization Committee, State staff or State contracted representatives. Only written testimony received at the above email address will be provided to committee members
11. A speaker's waiting list will be kept and speakers will be allotted time to speak, in the order speaking requests were received, only if cancellations occur.

12. Speakers are allowed only one four minute time slot in up to two individual drug classes.
13. Speakers may only provide testimony regarding drugs included in the specific drug class assigned to each four minute time slot.
14. The Committee Chair or designee may modify the time allotted to a speaker for comment as necessary to facilitate the work of the Committee.
15. Multiple speakers per company or organization will be permitted within the same four minute time slot per drug class.
16. All speakers are required to disclose who they represent, including any financial relationships and conflict of interest. This is to be done on the Speaker Conflict of Interest disclosure form as well as when addressing the Prior Authorization Advisory Committee
17. Speakers will be required to state their name, organization represented and the drug name(s) and class applicable to their testimony.
18. Speakers will be limited to clinical, scientific and/or personal experience testimony. Testimony regarding pricing is not permitted.
19. Time will be allotted for Committee members to ask questions of the speakers after testimony has been heard on each drug class.

1.5 Disclosure of Conflict of Interest and Confidentiality Requirements

The Chair of the Committee or authorized designee is authorized and directed to see that the following policies are adhered to:

Disclosure of Conflict of Interest

1. The Committee will operate in a manner that ensures the objectivity and credibility of its recommendations. To that end, each Committee member will be required to execute an agreement to disclose conflicts of interest and will have an ongoing duty to disclose any conflicts of interest to the Committee Chair and the Department.
2. A member of the Committee shall disclose a conflict of interest at the beginning of consideration of any matter in which the member has or may have a conflict of interest, or at the point during consideration when a potential conflict of interest becomes apparent to the member. After disclosure, the member may continue to participate in discussion, but shall abstain in any vote taken. Minutes of the meeting will reflect the disclosure and abstention from voting. Any question as to whether a conflict of interest exists shall be referred to the Chair/Medicaid Director.
3. Committee members failing to report any conflict of interest in this area will be subject to immediate dismissal from the Committee.

A conflict of interest exists whenever:

- You, a member of your immediate family, or an organization with which you are associated has a substantial financial interest in the outcome of a matter; or
- The outcome of a matter may produce or assist in producing a substantial financial benefit, direct or indirect, for you, one or more members of your immediate family, or an organization with which you are associated; or
- You, a member of your immediate family, or an organization with which you are associated receive money or any other thing of value from a company or other organization that has a financial interest in the outcome of a matter.

"Immediate family" includes your spouse and any relative by marriage, lineal descent or adoption who receives more than one-half of his or her support from you or from whom you receive more than one-half of your support.

"Organization with which you are associated" includes any organization in which you or a member of your immediate family is a director, officer or trustee, or owns or controls, directly or indirectly, at least 10% of the outstanding equity or of which you or a member of your immediate family is an authorized representative or agent.

Confidentiality

Each Committee member must comply with all HIPAA requirements regarding disclosure of patient information.

Information about any Medicaid recipient is confidential and may be used or disclosed only for purposes directly related to Medicaid administration, as determined by the State Medicaid Agency. No member of the Wisconsin Medicaid Pharmacy Prior Authorization Committee ("Committee") may disclose to any person any information regarding any Medicaid recipient.

Some information not related to Medicaid recipients that members of the Committee may obtain in the course of their participation on the Committee may qualify as trade secret under Wisconsin law. Such information will be clearly identified as such. No member may disclose any trade secret information obtained in the course of participation on the Committee. If a member receives a request to disclose such information, the member shall refer the request to the Chair/Medicaid Director.