For drug-specific prior authorization information, please contact the Medicaid Drug Prior Authorization Unit @ Mountain-Pacific 1-800-395-7961
BIOSIMILARS: A BASIC PRIMER (CONTINUED)

- Biosimilarity and/or interchangeability between the proposed biosimilar and the reference product must be established, but not separate safety and efficacy of the biosimilar compared to the reference product.
- Requirements for FDA biosimilar approval include:
  - Same mechanism of action, route of administration, dosage form, and strength as reference drug,
  - Same (or fewer) indications than approved for the reference product,
  - Manufacturing facilities must meet FDA standards,
  - Analytical studies demonstrating the biosimilar is “highly similar” except for inactive components, animal studies (assessing toxicity) and clinical studies sufficient to demonstrate safety/purity/potency.

A biosimilar must meet additional FDA standards to also be considered interchangeable with the reference product.
- A manufacturer may choose not to seek a designation of interchangeability with the reference product (i.e. Zarxio® is not interchangeable with Neupogen®)
- If interchangeability is sought, specific data/information must be provided:
  - to support the biosimilar is expected to produce the same clinical result as the reference product in any patient,
  - to demonstrate there is no difference in safety/efficacy if the patient is switched between the reference product and the biosimilar.
- The Purple Book (similar to the Orange Book for generics) lists licensed biological products and biosimilar (“B”) and/or interchangeable (“I”) status with the reference product. Available at:

References:

MONTANA MEDICAID PRIOR AUTHORIZATION CRITERIA UPDATES

Rexulti® - Brexipiprazole (Rexulti®) is an atypical antipsychotic agent indicated as adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD), and also for the treatment of schizophrenia. Its mechanism of action is combination partial agonist activity at serotonin 5-HT_{1a} and dopamine D_{2} receptors, and antagonism at serotonin 5-HT_{2a} receptors. Due to the availability of numerous other therapeutic alternative agents for these indications, the Montana Medicaid Drug Utilization Review Board (DURB) unanimously recommended implementation of the following clinical criteria for this brand-name medication:
- Patient must be 18 years of age or older
- Covered diagnoses are MDD and schizophrenia

Continued
MONTANA MEDICAID PRIOR AUTHORIZATION CRITERIA UPDATES (CONT.)

(Rexulti® criteria continued)

• MDD adjunctive treatment:
  » Patient must have an inadequate response, after at least four weeks of therapy, to at least two preferred antidepressant agents AND
  » Patient must have had an inadequate response or contraindication to aripiprazole and quetiapine as add-on therapy AND
  » Patient is concurrently using an antidepressant.
  » Dosing limitation of 1 tablet daily, up to maximum of 3 mg daily.

• Schizophrenia:
  » Patient must have had an inadequate response, after at least six weeks of therapy, to at least two preferred FDA-approved medications for schizophrenia
  » Dosing limitation of 1 tablet daily, up to maximum of 4 mg daily.

Of note:
  » No current published studies exist comparing aripiprazole and brexpiprazole, and therefore it is difficult to predict if any meaningful clinical differences exist.
  » In 2015, the first generic formulation of Abilify® (aripiprazole) was FDA approved.
  » Rexulti® is manufactured by Otsuka, the same manufacturer as Abilify®. Both medications have similar mechanisms of action.

Invega Trinza®- Paliperidone palmitate (Invega Trinza®) is an every 3-month injectable antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna® (a once-monthly paliperidone palmitate injection) for at least four months. Like all other available injectable atypical antipsychotic medications, it is administered by a healthcare professional. Due to the extremely long half-life once administered (~3-4 months depending on injection site) and the FDA requirement for first establishing compliance on Invega Sustenna®, the DURB has recommended implementation of the following clinical criteria:

• Patient must meet Medicaid criteria for all long-acting atypical injectables: compliance issue with oral medication and tolerability must be established with corresponding oral molecule,
• Patient must be 18 years of age or older,
• Must have a diagnosis of schizophrenia,
• Patient must have been compliant w/treatment using Invega Sustenna® for at least 6 months. This requirement is to ensure tolerability/effectiveness due to the time required for elimination once the medication is injected,
• Approval will be granted with compelling clinical rationale (non-compliance alone will not warrant coverage).

Aristada® - Aripiprazole lauroxil (Aristada®) is a long-acting (once monthly or once very 6 weeks, depending on dose) atypical antipsychotic injection indicated for the treatment of schizophrenia. Abilify Maintena®, a once-monthly aripiprazole injection, is currently the preferred long-acting injectable aripiprazole product.

» Aristada® is available in higher dosages (up to 882 mg) vs a maximum 400 mg for Abilify Maintena®.
» Place in therapy may be in clinical situations warranting higher dose than is available with the current preferred product, Abilify Maintena®.

The DURB has recommended implementation of the following clinical criteria:

• Patient must meet Medicaid criteria for long-acting atypical injectable: compliance issue with oral medication, tolerability established with corresponding oral molecule,
• Patient must be 18 years of age or older,
• Patient must have a diagnosis of schizophrenia,
• Compelling clinical rationale explaining why the preferred agent Abilify Maintena® cannot be prescribed. Example: Patient is not adequately controlled on 400mg Abilify Maintena® and requires higher dose,
• Concurrent oral aripiprazole is approved for 21 days per FDA labeling.

Sampling policy update:

Prior to 2016, patients sampled on atypical antipsychotics were allowed to continue under the Medicaid grandfathering (stable-therapy) policy on a non-preferred agent. This policy was implemented when few agents were available. After review of the numerous available preferred agents, the DUR board recommended to discontinue this policy. Samples will no longer qualify for grandfathering purposes for atypical antipsychotic agents. No other classes allow samples for grandfathering purposes.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>By Dollars</th>
<th># of Patients</th>
<th>Drug Name</th>
<th>By Rx Count</th>
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<tbody>
<tr>
<td>Aripiprazole</td>
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<td>Hydrocodone/Acetaminophen</td>
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*excludes injectable drugs except insulins (dollars are pre-rebate)