October 23, 2017

Authors: George Kitchens and Allison Scott

OREGON HEALTH AUTHORITY (MEDICAID)

Re: State is denying coverage of FDA approved medication through the Prioritized List of Health Services

EXECUTIVE SUMMARY

Oregon Health Plan (OHP) is using the Prioritized List of Health Services as a means to deny drug coverage without an opportunity for a provider to appeal and/or override via a prior authorization process except in special cases (see Denying Coverage). Prioritized Lines 1-475 are "funded" and lines 476 and greater are "non-funded". On September 28, 2017, the HERC placed the drug Emflaza on line 500 and Exondys 51 on line 660, both "non-funded' i.e. not covered. Emflaza was determined to provide "marginal benefit/low-cost-effectiveness compared to equally effective but much less expensive alternative corticosteroids". Exondys 51 was determined to provide "no clinically important benefit".

BACKGROUND

Oregon Medicaid 1115 waiver was initially established in 1994. It was recently renewed on January 12, 2017 and is renewed through June 30, 2022. The demonstration waiver provides the state additional flexibility to expand eligibility to individuals not otherwise eligible for Medicaid or CHIP; provide new services not typically covered by Medicaid; and use innovative service delivery systems that improve care, increase efficiency, and reduce costs. OHP Plus is Oregon's health plan, covering all ages under 65, excluding pregnant adults and Medicare eligible adults.

"One of the distinguishing features of the OHP demonstration is that OHP Plus benefits are based on the Prioritized List of Health Services, which ranks condition and treatment pairs by priority, from the most important to the least important, representing the comparative benefits to the entire population to be served. The prioritization of the list is based on the clinical and cost effectiveness of services." (CMS Waiver, page 18)

OREGON 1115 WAIVER

The below paragraphs are taken directly from the 1115 Waiver. Artia has underlined a few notable phrases. The Waiver can be accessed through the resources at the end of this document.

Oversight—The Health Evidence Review Commission (HERC)

The Health Evidence Review Commission (HERC) - The Health Evidence Review Commission (HERC) prioritizes health services for the Oregon Health Plan. The HERC is administered through the Health Policy & Analytics Division. The Commission consists of thirteen members appointed by the Governor, and includes five physicians, two health consumers, one dentist, one behavioral health representative, one complementary and alternative medicine representative, one insurance industry representative, one retail pharmacist and one public health nurse. The Health Evidence Review Commission performs a biennial review of the Prioritized List and will amend the List as required. (Page 18)

Modifications to the Prioritized List

Modifications to the Prioritized List require federal approval through submission of an amendment, as described in STC 7 in order to ensure the Prioritized List is comprehensive enough to provide Medicaid beneficiaries with an appropriate benefit package. A current version of the prioritized list of health services is maintained by the state of Oregon at the following website linked here. During the demonstration period and as specified below the state will not reduce benefits. (Page 18)

Ordering of the Prioritized List

The Prioritized List is ranked from most important to least important representing the comparative benefits of each service to the population to be served. The Commission uses clinical effectiveness, cost of treatment and public values obtained through community meetings in ordering the list. In general, services that help prevent an illness were ranked above those services which treat the illness after it occurs. Services prioritized low on the list are for conditions that (a) get better on their own or for which a home remedy is just as effective (e.g. common colds); (b) are primarily cosmetic in nature (e.g. benign skin lesions); or (c) have no effective treatments available (e.g. metastatic cancers). (Pages 18-19)

Updating the Prioritized List

The Commission is charged with updating the list for every regular legislative session occurring in odd-numbered years. The Oregon State Legislature determines how much of the list to cover (subject to federal approval), thus setting a health care budget. Under current statutes, the Legislature can fund services only in numerical order and cannot rearrange the order of the list. (Page 19)

Non-covered Condition and Treatment Pairs

In the case of non-covered condition and treatment pairs, Oregon must direct providers to inform patients of appropriate treatments, whether funded or not, for a given condition, and will direct providers to write a prescription for treatment of the condition where clinically appropriate. Oregon must also direct providers to inform patients of future health indicators, which would warrant a repeat visit to the provider.

The state must adopt policies that will ensure that before denying coverage for a condition/treatment for any individual, especially an individual with a disability or with a co-morbid condition, providers will be required to determine whether the individual could be furnished coverage for the problem under a different covered condition/treatment. In the case of a health care condition/treatment that is not on the prioritized list of health services, or is not part of the benefit package, but is associated with a co-morbid condition for an individual with a condition/treatment that is part of the benefit package, if treatment of the covered condition requires treatment of the co-morbid condition, providers will be instructed to provide the specified treatment. The state shall provide, through a telephone information line and through the applicable appeals process under subpart E of 42 CR Part 431, for expeditious resolution of questions raised by providers and beneficiaries in this regard. (Page 19)

Changes to the Prioritized List

Changes to the Prioritized List are subject to the approval processes as follows:

i. The state will maintain the cutoff point for coverage at the same position on the List relative to the 2012-2013 List for the remainder of the demonstration as noted above in subparagraph (g). For a legislatively directed line change to increase benefit coverage or a legislatively approved biennial list with substantive updating of benefits due to new evidence, an amendment request (in compliance with STC 7 will be submitted to CMS and consideration by the CMS medical review staff. Any increase in the benefit package above the core set of fixed services shall not require approval, but shall be subject to the requirements of budget neutrality as described in Section XIII.

ii. For interim modifications and technical changes to the list as a result of new and revised national codes, new technology, diagnosis/condition pairing omissions, or new evidence on the effectiveness or potential harm of a service already appearing on the List, CMS will be notified of changes.

iii. For a change to the list not defined above that meets the terms of STCs 6 and 7, an amendment request. (Pages 19-20)

Amendment Process (STC 7)

Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based upon non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a viable amendment request as found in these STCs, required reports and other deliverables required in the approved STCs in a timely fashion according to the deadlines specified herein.

Amendment Process (STC 7) continued…

Amendment requests will be reviewed by the Federal Review Team and must include, but are not limited to, the following:

a. An explanation of the public process used by the state to reach a decision regarding the requested amendment including the tribal consultation. The state must provide documentation of the state's compliance with the tribal consultation requirements outlined in STC 15. Such documentation shall include a summary of the tribal comments and identification of proposal adjustments made to the amendment request due to the tribal input;
b. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality expenditure cap. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level though the approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as result of the proposed amendment which isolates (by Eligibility Group) the impact of the amendment;
c. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and
d. If applicable, a description of how the evaluation design must be modified to incorporate the amendment provisions (Page 12)

RESOURCES

Oregon Health Care Authority 1115 Waiver

Prioritized List

HERC Meeting Materials, September 2017

CONSIDERATIONS FROM THE ARTIA TEAM

1. Is the denial of drug coverage in conflict with the access requirements of the CMS Medicaid Rebate agreement? It appears that there is no exclusion of the CMS Rebate agreement in the 1115 Waiver.

2. Is it not the FDA's job to determine drug approval and drug effectiveness?

3. If states require additional studies, data, etc. will that not drive up the cost of new drugs?

4. Do states have comparable resources to adequately evaluate clinical trials and supporting data as the FDA does?