Zubsolv® Transition

To

Preferred Drug List (PDL)

Frequently Ask Questions (FAQ)

The Department received questions from providers regarding the announced transition from coverage for the use of Suboxone® Film to the use of Zubsolv® tablets. The transition goes into effect on July 1, 2016.

Question: When will Zubsolv® sublingual tablets be preferred on the Maryland Medicaid Preferred Drug List (PDL)?

Answer: Effective July 1, 2016

Question: Will the Maryland Medicaid Preferred Drug List (PDL) only include Zubsolv® sublingual tablets as the preferred agent in the Opioid Dependence Treatments class?

Answer: Yes, the Maryland Medicaid PDL will only include Zubsolv® sublingual tablets as the preferred Opioid Dependence Treatments agent. However, other agents in this class will be available with a PDL prior authorization (PA) by the prescriber. These other agents include Suboxone® Film, Bunavail® Film, and the generic buprenorphine/naloxone sublingual tablets.

Question: Why does Medicaid not allow medical providers access to all formulations and brands?

Answer: The decision to only cover Zubsolv® sublingual tablets was not made in haste; the P&T Committee, during their May, 5th 2016 meeting, received extensive clinical and financial data to assist in the deliberations. At the in-person P&T meeting, the Committee received additional briefings from CMS and our PDL vendor Magellan Health (Magellan presented three options for the coverage of these products); the committee ultimately chose to advise the move of Suboxone® Film to non-preferred. Other agents in this class will be available with a PDL prior authorization (PA) by the prescriber. These other agents include Suboxone® Film, Bunavail® Film, and the generic buprenorphine/naloxone sublingual tablets.

Question: What Zubsolv® sublingual tablet, Suboxone® Film, Bunavail® Film and buprenorphine/naloxone sublingual tablet strengths will Medicaid reimburse for?

Answer: For the Maryland Medicaid Pharmacy Program the Point of Sale (POS) setting will cover all FDA-approved strengths for these products. As of July 1, 2016, Zubsolv® sublingual tablets will not require a PDL PA; however, the other products will require a

PDL PA. Quantity Limits do apply for all products. For the Opioid Treatment Programs (OTPs) Medicaid will cover Zubsolv® using 2 HCPC codes which have associated strengths of 1.4-2.9 mg and 5.7 mg. Similar to the current J8499 codes, the HCPCS codes listed in the next response will be billable in multiples until clinical dose is reached.

Question: What is Medicaid's reimbursement rate for each of the Zubsolv® sublingual tablet strength that Medicaid will authorize?

Answer: The Maryland Medicaid Pharmacy Program at the Point of Sale (POS) setting will reimburse pharmacy providers as required under COMAR 10.09.03.07.

For OTPs the following codes and reimbursement rates will be covered:

J0572 (modifier 51) Zubsolv® 1.4-.36 MG Tablet	$ 3.69 (NDC: 54123-0914-30)
J0572 (no modifier) Zubsolv® 2.9-.71 MG tablet	$ 7.39 (NDC: 54123-0929-30)
J0573: Zubsolv® 5.7-1.4 MG tablet	$ 7.39 (NDC: 54123-0957-30)

Question: How will this change affect OTPs that DISPENSE Suboxone®.

Answer: For OTPs that dispense the drug in their facility, the Department is allowing for a three month period during to make a clinical transition from the Suboxone® Film to the Zubsolv® tablets. Effective 7/1/2016, any new patients who are appropriate for receiving buprenorphine as treatment for their addiction in an OTP setting would need to be initiated on Zubsolv®. Only in cases where an OTP has a patient for whom Zubsolv® is contraindicated, an exception process will be made available through Beacon Health Options, the Department's ASO. Use of this exception process is under development as of this writing but will be clinically managed for a limited period of time **and will require re-authorization at to be determined** intervals.

Question: Since Medicaid currently requires Suboxone® film for reimbursement, OTPs have inventory to utilize, before purchasing tablets. Will Medicaid reimburse OTPs for the film in stock until an inventory of tablets is secured?

Answer: Maryland Medicaid will not reimburse for unused stock. Providers should contact the manufacturer for inquiries related to return of unused stock. During the transition period of 3 months providers should work with their pharmaceutical vendor regarding unused stock.

Question: Providers are concerned about impact to our EHR systems and will require re-training to add or change these codes.

Answer: The Department appreciates providers' efforts to complete the necessary steps for a smooth transition which includes the updates needed to Electronic Health Records systems. The codes provided in this FAQ should assist providers in this process.

Question: Could OTPs be exempt from this new restriction?

Answer: OTPs are not exempt from this change, however, a three month transition period has been added to help providers facilitate the change in transitioning from Suboxone® film. In addition, the Department will work with the ASO to develop a clinically managed exception process. In general, **OTPs need to change to Zubsolv® effective 7/1/2016, and as noted above, should induce new patients to Zubsolv® unless contraindicated.** The manufacturer of Zubsolv® has offered to assist providers with questions regarding the transition and has reached out to existing providers through provider stakeholder groups and has been in contact with many OTPs.

Question: Will the state be reaching out to physicians who prescribe Suboxone® Film to ensure they understand the differences between the Film and tablets and the impact on patients?

Answer: Maryland Medicaid has sent letters to all prescribers who prescribed Suboxone® Film for their patients in the last 12 months, to inform them that effective July 1, 2016, Zubsolv® sublingual tablets will be preferred and Suboxone® Film will require a PDL PA. The letter included information for the prescribers on how to obtain a PDL PA, if and when necessary. Finally, the letter included a conversion chart from Suboxone® sublingual tablets, including generic equivalents, to Zubsolv® sublingual tablets dosage strengths.

Question: The change from Suboxone® Film may require modification of many OTP and provider Policies and Procedures. Some of these changes for OTPs that are located within hospital or multi-site systems must be approved through Quality Assurance, Legal and other committees which take additional time.

Answer: The Department appreciates the efforts of providers to fast track changes in policy and procedure manuals in order to accommodate this change.

Question: Changes in medication format and doses require meetings with patients as patients will require education and reassurance.

Answer: The Department recognizes this is a change for providers and has received assurance from the manufacturer of Zubsolv® that pharmaceutical representatives will be available to provide support and education to providers through individual and group outreach as well as through webinar format, as providers make the transition. In addition, the Department would expect that as part of meeting Federal requirements to have face to face meetings with patients that appropriate counseling including medication counseling would be offered by the provider.

Snapshot of Impact to OTPs:

- OTPs will have a three month transition ending 9/30/2016 to assist their patients in switching to the preferred medication. Providers who need additional clinical assistance should reach out through their pharmaceutical representative to address clinical protocols of the medication.
- New patients as of 7/1/2016 should only receive the preferred medication unless clinically contraindicated.
- There is no reimbursement from Medicaid for existing/remaining supply, therefore providers should use the three months to work with their pharmaceutical representative to determine if unopened / unused medications can be returned.