



New York State Medicaid Drug Utilization Board Meeting Agenda

The Drug Utilization Review (DUR) Board will meet September 15, 2016, from 9:00 a.m. to 4:00 p.m., Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

Agenda Items

A. Preferred Drug Program (PDP) Reviews

The DUR Board will review therapeutic classes listed below, as they pertain to the PDP.

- The DUR Board will review clinical and financial information, to recommend preferred and non-preferred drugs.
- For therapeutic classes currently subject to the PDP, the DUR Board will only consider clinical information which is new since the previous review of the therapeutic class and then consider financial information.

New clinical information may include a new drug or drug product information, new indications, new safety information or new published clinical trials (comparative evidence is preferred, or placebo controlled when no head-to-head trials are available). Information in abstract form alone, posters, or unpublished data are poor quality evidence for the purpose of review and submission is discouraged.

- Those wishing to submit clinical information must do so in an electronic format by September 1, 2016 or the DUR Board may not have ample time to review the information.

1. Hepatitis C Agents – Direct Acting Antivirals

(Previous review date: April 27, 2016)

Copegus (ribavirin), Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Moderiba (ribavirin), Olysio (simeprevir), Rebetol (ribavirin), Ribasphere (ribavirin), ribavirin, Sovaldi (sofosbuvir), Technivie (ombitasvir/paritaprevir/ritonavir), Viekira Pak (ombitasvir/paritaprevir/ritonavir/ dasabuvir), Viekira XR (ombitasvir/paritaprevir/ritonavir/dasabuvir), Zepatier (elbasvir/grazoprevir)

2. ARBs Combinations

(Previous review date: April 15, 2011)

Atacand HCT (candesartan cilexetil/hctz), Avalide (irbesartan/hctz), Azor (amlodipine/olmesartan medoxomil), Benicar HCT (olmesartan medoxomil/hctz), Byvalson (nebivolol/valsartan), candesartan/ HCTZ, Diovan HCT (valsartan/hctz), Edarbyclor (azilsartan medoxomil/chlorthalidone), Entresto (sacubitril/valsartan), Exforge (amlodipine/valsartan), Exforge HCT (amlodipine/valsartan/hctz), Hyzaar (losartan/hctz), irbesartan/hctz, losartan/hctz, Micardis HCT (telmisartan/hctz),

telmisartan/amlodipine, telmisartan/hctz, Tribenzor (olmesartan/amlodipine/hctz), Twynsta (telmisartan/amlodipine), valsartan/amlodipine, valsartan/amlodipine/hctz, valsartan/hctz

3. Pulmonary Arterial Hypertension (PAH) Agents, Oral
(Previous review date: September 18, 2014)
Adempas (riociguat), Letairis (ambrisentan), Opsumit (macitentan), Orenitram (treprostinil), Tracleer (bosentan), Uptravi (selexipag)
4. Anticonvulsants - Second Generation
(Previous review date: April 22, 2015)
Banzel (rufinamide), Briviact (brivaracetam), felbamate, Felbatol (felbamate), Fycompa (perampanel), gabapentin (capsule, solution, tablet), Gabitril (tiagabine), Keppra/Keppra XR (levetiracetam), Lamictal/ Lamictal ODT/Lamictal XR (lamotrigine), lamotrigine, lamotrigine ER, lamotrigine ODT, levetiracetam, levetiracetam ER, Lyrica (pregabalin), Neurontin (gabapentin), Onfi (clobazam), Potiga (ezogabine), Qudexy XR (topiramate), Sabril (vigabatrin), Spritam (levetiracetam), tiagabine, Topamax (topiramate), topiramate, topiramate ER, Trokendi XR (topiramate ER), Vimpat (lacosamide), Zonegran (zonisamide), zonisamide
5. Multiple Sclerosis Agents
(Previous review date: April 22, 2015)
Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Glatopa (glatiramer acetate), Gilenya (fingolimod), Plegridy (peginterferon beta-1A), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Zinbryta (daclizumab)
6. Serotonin Receptor Agonists (Triptans)
(Previous review date: April 15, 2011)
Drugs Affected: almotriptan, Amerge (naratriptan), Axert (almotriptan), Frova (frovatriptan), frovatriptan, Imitrex (sumatriptan nasal spray, tablet, vial), Imitrex kit (cartridge, pen) (sumatriptan), Maxalt (rizatriptan), naratriptan, Onzetra Xsail (sumatriptan inhalation powder), Relpax (eletriptan), rizatriptan, Sumavel DosePro (sumatriptan), sumatriptan (nasal spray, tablet, vial), sumatriptan kit (cartridge, pen), Treximet (sumatriptan/naproxen), Zembrace SymTouch (sumatriptan injection), zolmitriptan, Zomig (zolmitriptan)
7. Immunomodulators, Systemic
(Previous review date: April 22, 2015)
Actemra (tocilizumab subQ), Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Kineret (anakinra), Orencia (abatacept subQ), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Xeljanz XR (tofacitinib)

B. Drug Utilization Reviews (DUR)

The DUR Board will review the following pharmacotherapies and recommend clinical criteria and/or interventions to ensure appropriate utilization:

1. Gabapentin - Gralise/Gralise ER, Horizant, Neurontin
2. Injectable Anticoagulants - dalteparin (Fragmin), enoxaparin (Lovenox), fondaparinux (Arixtra)
3. Products for Irritable Bowel Syndrome (IBS) - linaclotide (Linzess), lubiprostone (Amitiza), alosetron (Lotronex), eluxadoline (Viberzi), rifaximin (Xifaxan)

C. Clinical Editing Reviews

The DUR Board will be presented with utilization information associated with current clinical criteria and/or interventions:

1. sodium oxybate (Xyrem)
2. tasimelteon (Hetlioz)
3. memantine ER (Namenda XR)
4. tetrabenazine (Xenazine)
5. lomitapide (Juxtapid) and mipomersen (Kynamro)
6. palivizumab (Synagis)
7. serotonin receptor agonists (Triptans)

Agenda Timeline (subject to change based on meeting proceedings)

| | |
|---------------|--|
| 9:00 - 9:15 | Welcome & Introductions |
| 9:15 - 10:15 | Public Comment Period |
| 10:15 - 11:30 | PDP Clinical Reviews |
| 11:30 - 1:00 | Lunch/Executive Session (PDP financial review) |
| 1:00 - 1:30 | PDP Recommendations |
| 1:30 - 3:00 | Drug Utilization Reviews |
| 3:00 - 3:45 | Clinical Editing Reviews |
| 3:45 - 4:00 | Final Comments and Adjournment |

Interested parties must notify the Department of Health (DoH) by September 7, 2016 of their request to address the DUR Board during the public comment period. Requests may be made by calling 518-486-3209 or e-mailing dur@health.ny.gov. (please reference DUR Board Speaker Request).

Public comments are limited to the agenda items listed above. In addition, public comments for therapeutic classes currently subject to the PDP are limited to new clinical information since the previous review. Comments must be brief (2 minutes) and the total comment period will not exceed sixty (60) minutes. DoH reserves the right to limit the number of interested parties providing public comment in order to meet timelines and accomplish meeting objectives.

All written statements, must be received in an electronic format by September 7, 2016. Written statements should summarize key points and may not exceed two (2) pages in length. Any studies cited should be referenced, with the primary source of funding included.

All clinical information must be received in an electronic format by September 1, 2016, or the DUR Board may not have ample time to review the information. For the therapeutic classes currently subject to the PDP, submitted clinical information must be new since the previous review of the therapeutic class.

Any information regarding the DUR Board meeting must be sent to the DoH to ensure distribution to all DUR Board members. Interested parties should not contact or send any information directly to DUR Board members.