**Drug Utilization Review (DUR) Committee**

November 21st 2014

**Members Present**

Robin Cooke, PharmD, CGP
Jenny Love, MD (telephonic)
John Pappenheim, MD (telephonic)
Maggi Rader, CNM
Chuck Semling, PharmD
Chad Hope, PharmD (DHSS)
Erin Narus, PharmD (DHSS)

**Members Absent**

**Non-Members Present**

Tolu Balogun, PharmD (Magellan)
Julie Pritchard, PharmD (Magellan)
Verne Boerner (ANTHC)
Dr. Ward Hurlburt, MD (DHSS)
Lisa Valaika (Drug Rep, *tele*)
Tzeli Triantafillou (Drug Rep, *tele*)
Dan (last name unk.) (Drug Rep, *tele*)
Deirdre Monroe (Drug Rep, *in person*)
Jim Colyer (Drug Rep, *in person*)

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Meeting started at approximately 1:02pm; Attendance was taken
Teleconference access available

Welcome
Open floor to members for comments, questions, concerns
no issues brought forward
Review of minutes from September 19th, 2014
approved unanimously with addition of Bactroban cream PA information to be added
Review of agenda

**ProDUR**

- **Review of existing Prior Authorizations, Quantity Limits, Edits**
  - Botulinum Toxin
    - Previous review was April 2011
    - New FDA indications and new product availability prompted review
    - New criteria emphasizes patient safety
    - Proposed changes require 30 day trial of 2 previously tried oral agents
    - Criteria also requires documented clinical efficacy (improvement from initial baseline) when utilized for chronic migraine.
    - Utilization review will occur in 6 months

    APPROVED; UNANIMOUS
    http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Botulinium%20Toxin%20Criteria.pdf

  - Hepatitis C, Direct Acting Agents
    - There were previously individual criteria for each available agent – Olysio and Sovaldi – approved in April 2014
    - Proposed criteria incorporates previous criteria into single class-based criteria
    - Congruent with AASLD and IDSA guidelines, criteria will continue to prioritize patients with Metavir Fibrosis scoreF3 and F4 to ensure those patients in imminent need are treated; will expand criteria to include those individuals with Metavir Fibrosis score F2 with severe extrahepatic complications, specifically

Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (systemic vasculitis, pleural effusions, nephrotic syndrome, membranoproliferative glomerulonephritis.
    - Proposed criteria requires documentation of efficacy at 4 week check (RVR – rapid virologic response) with initial approvals for all treatment regimens only approved for 8 week period with renewal authorization requiring submission of HCV RNA at treatment week 4
    - Motion to TABLE vote on item #2 of "Criteria for Approval" (marijuana language) until next meeting (January) with the understanding that marijuana still remains an illicit drug in Alaska within that period.
      APPROVED; UNANIMOUS
    - Motion to APPROVE draft Hepatitis C Direct Acting Agent criteria with the omission of reference to marijuana on line 2 of "Criteria for Approval" and line 1 of "Criteria for Denial".
      APPROVED; UNANIMOUS
      http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/HCV-DAA_PA_Criteria.pdf

  - Intuniv - tabled until January meeting

- **Proposed new Prior Authorizations, Quantity Limits, Edits**
  - Imbruvica
    - Due to high cost of product and specific approved indications
    - Criteria in alignment with FDA approved labeling
    - FDA indications include treating Mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) in patients who have received at least one prior therapy; and chronic lymphocytic leukemia 17p deletion.

    APPROVED; UNANIMOUS
    http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Imbruvica.pdf

  - Zydelig
    - Criteria in alignment with FDA approved labeling
    - Indication is for treating relapsed CLL in combination with rituximab; relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small cell lymphomatic lymphoma (SLL) in patients who have tried at least two prior systemic therapies

    APPROVED; UNANIMOUS
    http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Zydelig.pdf

  - Entyvio
    - Review was prompted by concerns of inappropriate utilization; this is evidenced in requests received with incomplete dosing and inappropriate administration frequencies.
    - FDA indicated for the treatment of Crohn's disease and Ulcerative colitis.
    - Proposed criteria requires utilization of Crohn's disease activity index >220 and for patients receiving corticosteroids at baseline, documentation of an initial attempt or plan to taper the corticosteroids.
    - Reauthorization is required for therapy beyond a duration of 14 weeks

    APPROVED; UNANIMOUS

http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Entyvio.pdf

- Stelara (Subcutaneous)
  - Stelara is not a first line agent; utilization cost hits upper limit of cost exceeds max;
  - There are concerns of inappropriate utilization as seen in requests received that include inappropriate dosing.
  - Proposed changes to presented criteria include:
    - Removal of definition of therapeutic benefit (short and long term)
    - Add "not on concurrent photo-therapy" to approval criteria
    - Correct dosage form from 'infusion' to 'injection'

  APPROVED, WITH ABOVE CHANGES; UNANIMOUS
  http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Stelara.pdf

MOTION TO TABLE REST OF AGENDA TO NEXT MEETING; PASSED UNANIMOUSLY.

Meeting adjourned

**Next Meeting:**
January 16th 2015 at 1:00pm