DEPARTMENT OF HUMAN SERVICES

Meeting Minutes: Drug Formulary Committee - DRAFT

Date and Time:	August 10, 2022; 5:15 – 9 p.m.
Minutes prepared by:	Naana Osei-Boateng and Dave Hoang
Location:	Virtual Meeting via Zoom or In-person Meeting at The Department of Human Services (DHS) Elmer Andersen Building, Room 2370

Attendance

- Members in attendance: Stuart Williams, JD; Kelly Ruby, PharmD; Monica Brands, RPh; Kathryn Lombardo, MD; Margaret Artz, RPh, PhD; Kathryn Montag-Shafer, PharmD; Tim Cernohous, PharmD; James Phillips, MD; Michael Sprehe, MD; Ronda Chakolis, PharmD;
- Members absent: Tsewang Ngodup, MD; Kyle Lehenbauer, MD; Mary Mescher Benbenek, APRN, PhD
- DHS staff present: Dave Hoang, PharmD, MBA; Nathan Chomilo, MD
- Others in attendance: Katie Counts, PharmD; Umang Patel, PharmD; Naana Osei-Boateng, PharmD

Report of the Chair

- Stuart Williams presided over the meeting.

Approval of Minutes

- The committee reviewed and accepted the Minutes from the May 2022 meeting as presented.

DHS Housekeeping

- The Drug Formulary Committee (DFC) is in the process of recruiting physician members to join the committee.

Old Business – None

New Business

Existing Specialty Drugs for Continued Prior Authorization (PA)

Consent Agenda Items

- The committee recommended to DHS by a unanimous vote that Synagis remain on PA with the proposed updated criteria.
- The committee recommended to DHS by a unanimous vote that Vijoice, Welireg, Tezspire, Recorlev and Korsuva remain on PA with the proposed criteria.

Specialty Drugs for Continued Prior Authorization (PA)

- The committee discussed Tavneos and recommended to DHS by a unanimous vote that Tavneos remain on PA with the proposed criteria, with the following change:
    - Amend 4th bullet point under Initial approval criteria to read: Physician has assessed disease severity utilizing an objective measure/tool (**i.e**., Birmingham Vasculitis Activity Score [BVAS])
- The committee discussed Vyvgart and recommended to DHS by a unanimous vote that Vyvgart remain on PA with the proposed criteria.
- The committee discussed Pemfexy and recommended to DHS by a unanimous vote that Pemfexy remain on PA with the proposed criteria.
- The committee discussed Opdualag and recommended to DHS by a unanimous vote that Opdualag remain on PA with the proposed criteria, with the following changes
    - Amend 2nd bullet point under Initial approval criteria to read: Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), severe immune-mediated adverse reactions (**e.g**., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, myocarditis, adverse skin reactions/rash, neurologic toxicities, etc.)
- The committee discussed Vabysmo and recommended to DHS by a unanimous vote that Vabysmo remain on PA with the proposed criteria, with the following change:
    - Amend 4th bullet point under Initial approval criteria to read: Therapy will not be used with other ophthalmic VEGF inhibitors (**e.g.**, aflibercept, brolucizumab-dbll, ranibizumab, pegaptanib, bevacizumab, etc.)
- The committee discussed Fleqsuvy and recommended to DHS by a unanimous vote that Fleqsuvy remain on PA with the proposed criteria.
- The committee discussed Pyrukynd and recommended to DHS by a unanimous vote that Pyrukynd remain on PA with the proposed criteria, with the following changes:
    - Amend 2nd bullet point under Initial approval criteria to read: Patient has a confirmed diagnosis of pyruvate kinase deficiency (PKD) as defined by the documented presence of at least 2 variant alleles in the PKLR gene, of which at least 1 was a missense variant **or PK enzyme deficiency**;
    - Removal of the 4th bullet point under Initial approval criteria
- The committee discussed Kimmtrak and recommended to DHS by a unanimous vote that Kimmtrak remain on PA with the proposed criteria.
- The committee discussed Vonjo and recommended to DHS by a unanimous vote that Vonjo remain on PA with the proposed criteria.
- The committee discussed Ryplazim and recommended to DHS by a unanimous vote that Ryplazimremain on PA with the proposed criteria.

- The committee discussed Enjaymo and recommended to DHS by a unanimous vote that Enjaymo remain on PA with the proposed criteria, with the following changes:

    - Amend 2nd bullet point under Initial approval criteria to read: Patient does not have an active chronic systemic infection (**e.g**., hepatitis B, hepatitis C, or HIV, etc.);
    - Amend 3rd bullet point under Initial approval criteria to read: Will not be used in combination with another complement-inhibitor therapy (**e.g.,** ravulizumab, eculizumab, pegcetacoplan, avacopan, etc.)
    - Amend 8th bullet point under Initial approval criteria to read: Other causes of CAD have been ruled out such as coexisting diseases or conditions (**e.g.** infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy, etc.)

- The committee discussed Tarpeyo and recommended to DHS by a unanimous vote that Tarpeyo remain on PA with the proposed criteria, with the following changes:
    - Amend 11th bullet point under Initial approval criteria to read: Approval is for the equivalent of 9.5 months in days and is not renewable.
    - Removal of the last two sentences in the background section of the document.

- The committee discussed Fyarro and recommended to DHS by a unanimous vote that Fyarro remain on PA with the proposed criteria, with the following changes:
    - Amend 1st bullet point under Universal criteria to read: Patient does not have a severe hypersensitivity to rapamycin derivatives (**e.g.**, sirolimus, everolimus, temsirolimus, etc.)
    - Amend 5th bullet point under Universal criteria to read: Patient has had no prior treatment with or will not be used in combination with other mTOR inhibitors (**e.g**., sirolimus, everolimus, temsirolimus, etc.);

Drugs for Continued PA

- The committee discussed Tyrvaya and recommended to DHS by a unanimous vote that Tyrvaya remain on PA with the proposed criteria, with the following change:
    - Amend 6th bullet point under Initial approval criteria to read: Patient has had a 3-month trial and failure of (or contraindication) to Restasis, cyclosporine 0.09% ophthalmic solution or cyclosporine 0.05% ophthalmic emulsion

- The committee discussed Ibsrela and recommended to DHS by a unanimous vote that Ibsrela remain on PA with the proposed criteria, with the following change:
    - Amend 5th bullet point under approval criteria to add **glycerin suppository** to the products listed.

Adjournment

- The meeting was adjourned at approximately 8:37 p.m. Central Time.