Approval of minutes from 3-29-2021. Meeting started at 5pm, ended at 6:15pm
Attending: Dr. Hagenstad, Dr. Sakar, Dr. Singh, Alok Gupta, Remco Witteveen, Chris Fenchak, Amy Tumlin, Shirlinda Thomas, Monique Campbell.

Issue:	Recommendations/Actions:
Pharmacy/Formulary/ Lab/AIC	1-25-21 meeting minutes were approved by Dr. Hagenstad and Dr. Singh. New Drugs - Dr. Hagenstad Note: in-services (virtual format during this time) are recommended for all new drugs and indications • **Pepaxto© (melphalan flufenamide) -** An alkylating drug indicated in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody • **Cosela© (trilaciclib) –** IV CDK4-6 inhibitor indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered within 4 hours prior to start of a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer **Indication and Label Updates – Dr. Sakar** • **Lorbrena© (lorlatinib)** approved by FDA for patients with mNSCLC whose tumors are ALK-positive Considered "most active" ALKi. May be used 1st or 2nd line • **Libtayo© (cemiplimab)** Non-Small Cell Lung Cancer (NSCLC) • for the first-line treatment of patients with NSCLC whose tumors have **high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%]** as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is: ▪ locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or • metastatic. o Basal Cell Carcinoma (BCC) • for the treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for mBCC may be contingent upon verification and description of clinical benefit. • **Enhertu© (fam-trastuzumab deruxtecan-nxki)** approved by FDA for adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen. (1.15.21) • Dosing (note, different dosing vs. Breast Cancer): The recommended fam-trastuzumab deruxtecan-nxki dose for gastric cancer is **6.4 mg/kg** administered as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity • **Opdivo© (nivolumab)/ Cabometyx© (cabozantinib)** approved in combination as first-line treatment for patients with advanced renal cell carcinoma (RCC).

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The recommended dose is nivolumab 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity

Darzalex Faspro© (daratumumab hyaluronidase) in combination CyBorD now approved in combination newly diagnosed light chain (AL) amyloidosis.

Dosing: 1800 mg SQ

Keytruda© (pembrolizumab) in combination with platinum and fluoropyrimidine based chemotherapy for patients with metastatic or locally advanced esophaegeal or gastroesophageal (GEJ) (tumors with epicenter 1 to 5 centimeters above gastroesophageal junction) carcinoma who are not candidates for surgical resection or definitive chemoradiation.
Padcev (enfortumab vedotin-ejfv) now has NCCN category 1 approval for metastatic urothelial carcinoma.

Withdrawn Indications: Accelerated approvals, didn’t meet end points
<table>
<tr><th>Date</th><th>Medication</th><th>Withdrawn Indication</th></tr>
<tr><td>1/4/2021</td><td>Opdivo©</td><td>3rd line SCLC</td></tr>
<tr><td>2/23/2021</td><td>Imfinzi©</td><td>Previously treated locally advanced or metastatic bladder CA</td></tr>
<tr><td>3/2/2021</td><td>Keytruda©</td><td>3rd line SCLC</td></tr>
<tr><td>3/8/2021</td><td>Tecentriq©</td><td>Metastatic bladder CA previously treated with platinum therapy</td></tr>
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<u>Pharmacy updates</u>

Hepatitis B/C testing
The following medications have BLACK BOX WARNINGS regarding Hepatitis reactivation, fulminant hepatitis and hepatic failure and death:

<u>Gazyva© (obinutuzumab)</u>
<u>Ocrevus© (ocrelizumab)</u>
<u>Rituximab or biosimilars</u>
<u>Rituxan Hycela© Rituximab hyaluronidase</u>

Please make sure hep B/C lab ordering occurs at time the protocol is ordered
Initiation of therapy should be delayed, whenever possible, until results of testing available, and appropriate for administration of these agents. Provider should evaluate if delay is appropriate, on case by case basis.

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<tr><td><u>Covid-19 Updates</u></td><td>Covid-19 Guidelines are available on the GCS Intranet. See updated information on treatment availabilities. – Remco Witteeven</td></tr>
<tr><td>Lab/Pharmacy/Clinical</td><td>Drug Shortages: Certain doses of Lupron and Epipen - Chris Fenchak
Lab Monitoring updates (Hep B/C testing):
The following medications have BLACK BOX WARNINGS regarding Hepatitis reactivation, fulminant hepatitis and hepatic failure and death:

<u>Gazyva© (obinutuzumab)</u>
<u>Ocrevus© (ocrelizumab)</u>
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Issue:	Recommendations/Actions:
	▪ Rituximab or biosimilars ▪ Rituxan Hycela© Rituximab hyaluronidase • **Please make sure hep B/C lab ordering occurs at time the protocol is ordered** • ○ Initiation of therapy should be delayed, whenever possible, until results of testing available, and appropriate for administration of these agents. Provider should evaluate if delay is appropriate, on case by case basis. • Chris Fenchak has update all of the relevant protocols as a task assigned to him ▪ Pump library – Chris Fenchak has updated the pump library. Will make sure that pumps in each of the 4 clinics get the same update. ▪ There was a suggestion to remove leucovorin from protocols that do not have a 5-FU bolus or it has been removed due to toxicity. This was agreed to by the committee and Dr. Hagenstad sent out emails to all of the physicians about this. Relevant protocols will be updated on day of service if labs dictate removing 5-FU push then leucovorin will be deleted by pharmacist. ▪ Another suggestion was made to remove Mannitol from Cisplatin protocols. A study showing no benefit was forwarded to the group. To follow up in next meeting. ▪ There was question regarding dental clearance for bis-phosphonate injection/infusion. NSH does not require this. However, the patient is advised to consult with their dentist before start of therapy with a routine follow up. ▪ Based on information from the PI of Cinvanti, it was suggested to decrease the dose of dexamethasone to 12mg for all protocols containing Cinvanti. This was agreed by the committee and Chris Fenchak/Shirlinda/Monique will update all of the protocols.
Retail Pharmacy	Remco shared that we have the DEA number and State License. Waiting on the NPI number to start negotiation of contracts with vendors and wholesalers. Looking at projected opening of Late July or early August.
Education	
Next Meeting	May 31st (changed to June 14th)