Testimony
Engrossed Senate Bill 2290 - Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman

March 4, 2019

Chairman Weisz and members of the House Human Services Committee, I am Brendan Joyce, Administrator of Pharmacy Services with the Medical Services Division for the Department of Human Services (Department). I appear today to provide testimony on Engrossed Senate Bill 2290.

Engrossed Senate Bill 2290 would allow the Department to have step therapy for the Medicaid program for new prescriptions for cancer medications. For instance, Cabometyx® was approved by the Food and Drug Administration (FDA) on January 14, 2019 for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. If step therapy was implemented for this medication, it would simply ensure that any HCC patient receiving a prescription order for Cabometyx® was previously treated with sorafenib. For further examples and to show how FDA approvals are done, you will see all of the 2018 FDA approvals and safety notifications for hematology/oncology (cancer) medications in Attachment A with all of the similar situations highlighted. Blue highlight shows drugs approved to be used as first line, and yellow shows those whose approval specifically is not for first line use.

The step therapy would be completely modeled on Medicare Part B. Please reference the August 7, 2018 memorandum from the Centers for Medicare and Medicaid Services (CMS) outlining guidance allowing Medicare Advantage plans to utilize step therapy for Part B drugs (Attachment B).

The Department would not implement any step therapy protocol that is not already being used by Medicare Part B plans. Also, as required by section 50-24.6-04 of the

North Dakota Century Code, the Drug Use Review (DUR) Board would review any step therapy protocols prior to implementation. Since step therapy is based on clinical protocols and Food and Drug Administration approvals, the Department does not anticipate any fiscal impact. Also, given requirements for DUR Board review and approval, and the timeframes surrounding such, no step therapy would be implemented prior to calendar year 2020, and only then if Medicare Part B has approved the specific step therapy protocol.

This concludes my testimony, and I am happy to answer any questions you may have.

- FDA approved tagraxofusp-erzs (ELZONRIS™, Stemline Therapeutics), a CD123-directed cytotoxin, for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older. More information. December 21, 2019
- FDA approved ravulizumab-cwvz (ULTOMIRIS™, Alexion Pharmaceuticals, Inc.) for adult patients with paroxysmal nocturnal hemoglobinuria (PNH). More information. December 21, 2018
- FDA approved calaspargase pegol-mknl (ASPARLAS, Servier Pharmaceuticals LLC), an asparagine specific enzyme, as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years. This new product provides for a longer interval between doses compared to other available pegaspargase products. More Information. December 20, 2018
- FDA approved olaparib (LYNPARZA, AstraZeneca Pharmaceuticals LP) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. More Information. December 19, 2018
- FDA granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co. Inc.) for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC). More Information. December 19, 2018.
- FDA approved Herzuma (trastuzumab-pkrb, Celltrion Inc.) as a biosimilar to Herceptin (trastuzumab, Genentech Inc.) for patients with HER2-overexpressing breast cancer. More Information. December 14, 2018
- FDA approved romiplostim (NPLATE, Amgen Inc.) for pediatric patients 1 year of age and older with immune thrombocytopenia (ITP) for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. More Information. December 14, 2018
- FDA approved atezolizumab (TECENTRIQ, Genentech, Inc.), in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic non-squamous, non-small cell lung cancer (NSq NSCLC) with no EGFR or ALK genomic tumor aberrations. More Information. December 6, 2018
- FDA approved gilteritinib (XOSPATA, Astellas Pharma US Inc.) for treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. More Information. November 28, 2018
- FDA approved Truxima (rituximab-abbs, Celltrion Inc.) as the first biosimilar to Rituxan (rituximab, Genentech Inc.) for patients with CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) to be used as a single agent or in combination with chemotherapy. More Information. November 28, 2018
- FDA granted accelerated approval to larotrectinib (VITRAKVI, Loxo Oncology Inc. and Bayer) for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment. More Information. November 26, 2018
- FDA granted accelerated approval to venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) in combination with azacitidine or decitabine or lo w-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. More Information. November 21, 2018
- FDA approved glasdegib (DAURISMO, Pfizer Labs) in combination with low-dose cytarabine (LDAC), for newly-diagnosed acute myeloid leukemia (AML) in patients who are 75 years old

or older or who have comorbidities that preclude intensive induction chemotherapy. More Information. November 21, 2018

- FDA approved emapalumab (GAMIFANT, Novimmune SA), a monoclonal antibody that binds and neutralizes interferon gamma, for adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. More Information November 20, 2018
- FDA approved brentuximab vedotin (ADCETRIS, Seattle Genetics Inc.) in combination with chemotherapy for previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas. More information. November 16, 2018
- FDA granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. More Information. November 9, 2018
- FDA granted accelerated approval to lorlatinib (LORBRENA, Pfizer, Inc.) for patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease. More Information. November 2, 2018
- FDA approved pembrolizumab (KEYTRUDA, Merck & Co. Inc.) in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC)..More Information. October 30, 2018
- FDA approved talazoparib (TALZENNA, Pfizer Inc.), a poly (ADP-ribose) polymerase (PARP) inhibitor, for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2 negative locally advanced or metastatic breast cancer. Patients must be selected for therapy based on an FDA-approved companion diagnostic for talazoparib. More Information. October 16, 2018.
- FDA approved emicizumab-kxwh injection (HEMLIBRA, Genentech, Inc.) for prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients (ages newborn and older) with hemophilia A (congenital factor VIII deficiency) with or without factor VIII (FVIII) inhibitors. More Information. October 4, 2018
- FDA approved cemiplimab-rwlc (LIBTAYO, Regeneron Pharmaceuticals Inc.) for patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. More Information. September 28, 2018.
- FDA approved dacomitinib tablets (VIZIMPRO, Pfizer Pharmaceutical Company) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. More Information. September 27, 2018
- FDA granted regular approval to duvelisib (COPIKTRA, Verastem, Inc.) for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. In addition, duvelisib received accelerated approval for adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. More Information. September 24, 2018
- FDA approved moxetumomab pasudotox-tdfk (LUMOXITI, AstraZeneca Pharmaceuticals LP), a CD22-directed cytotoxin indicated for adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA). More Information. September 13, 2018

- FDA approved pembrolizumab (KEYTRUDA, Merck & Co., Inc.) in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, non-squamous non-small cell lung cancer (NSqNSCLC), with no EGFR or ALK genomic tumor aberrations. More Information. August 20, 2018.
- FDA updated the prescribing information for Keytruda (pembrolizumab) and Tecentriq (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible. FDA approved two different companion diagnostic tests, one for use with Keytruda and one for use with Tecentriq, More Information. August 16, 2018.
- FDA granted accelerated approval to nivolumab (Opdivo, Bristol-Myers Squibb Company Inc.) for patients with metastatic small cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy. More Information. August 16, 2018
- FDA approved lenvatinib capsules (Lenvima, Eisai Inc.) for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC). More Information. August 16, 2018
- FDA approved mogamulizumab-kpkc (Poteligeo, Kyowa Kirin, Inc.) for adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. More Information. August 8, 2018
- FDA approved lusutrombopag (Mulpleta, Shionogi Inc.) for thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure. More Information. July 31, 2018.
- FDA approved iobenguane I 131 (AZEDRA, Progenics Pharmaceuticals, Inc.) for adult and pediatric patients (12 years and older) with iobenguane scan-positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL) who require systemic anticancer therapy. More Information. July 30, 2018.
- FDA approved ivosidenib (Tibsovo, Agios Pharmaceuticals, Inc.) for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. More Information. July 20, 2018
- FDA expanded the indication for ribociclib (Kisqali, Novartis Pharmaceuticals Corporation) in combination with an aromatase inhibitor for pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. More Information. July 18, 2018
- FDA approved enzalutamide (XTANDI, Astellas Pharma US, Inc.), for patients with castration-resistant prostate cancer (CRPC). More Information. July 13, 2018
- FDA granted accelerated approval to ipilimumab (YERVOY, Bristol-Myers Squibb Company Inc.) for use in combination with nivolumab for the treatment of patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. More Information. July 10, 2018
- FDA has limited the use of Tecentriq and Keytruda for patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. More Information. June 19, 2018
- FDA approved encorafenib and binimetinib (BRAFTOVI and MEKTOVI, Array BioPharma Inc.) in combination for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. More Information. June 27, 2018

- FDA granted accelerated approval to pembrolizumab (Keytruda, Merck) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. More Information. June 13, 2018
- FDA approved bevacizumab (Avastin, Genentech, Inc.) for patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by single-agent bevacizumab, for stage III or IV disease after initial surgical resection. More Information. June 13, 2018
- FDA approved pembrolizumab (Keytruda, Merck and Co. Inc.) for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. More Information. June 12, 2018
- FDA granted regular approval to venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. More Information. June 8, 2018
- FDA approved methoxy polyethylene glycol-epoetin beta (Mircera, Vifor Pharma Inc.) for the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. More Information. June 7, 2018
- FDA approved Fulphila (pegfilgrastim-jmdb, Mylan GmbH) as a biosimilar to Neulasta (pegfilgrastim, Amgen, Inc.) to decrease the chance of infection as suggested by febrile neutropenia in patients with non-myeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia. More Information. June 4, 2018
- FDA approved avatrombopag (Doptelet, AkaRx Inc.) for thrombocytopenia in adults with chronic liver disease scheduled to undergo a procedure. More Information. May 21, 2018
- FDA approved Retacrit (epoetin alfa-epbx, Hospira Inc., a subsidiary of Pfizer Inc.) as a biosimilar to Epogen/Procrit (epoetin alfa, Amgen Inc.) for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and not on dialysis, use of zidovudine in patients with HIV infection, and the effects of concomitant myelosuppressive chemotherapy. It is also approved for the reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery. More Information. May 15, 2018
- FDA approves dabrafenib plus trametinib for anaplastic thyroid cancer with BRAF V600E mutation. More Information. May 4, 2018.
- FDA approved tisagenlecleucel (KYMRIAH, Novartis Pharmaceuticals Corp.) a CD19-directed genetically modified autologous T-cell immunotherapy, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. More Information. May 1, 2018.
- FDA granted regular approval to dabrafenib (TAFINLAR, Novartis Pharmaceuticals Corp.) and trametinib (MEKINIST, Novartis Pharmaceuticals Corp.) in combination for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. More Information. April 30, 2018
- FDA approved osimertinib (Tagrisso, AstraZeneca Pharmaceuticals LP) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have

epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. More Information. April 19, 2018

- FDA approved fostamatinib disodium hexahydrate tablets (TAVALISSE, Rigel Pharmaceuticals, Inc.) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. More Information. April 17, 2018
- FDA granted approvals to nivolumab and ipilimumab (Opdivo and Yervoy, Bristol-Myers Squibb Co.) in combination for the treatment of intermediate or poor risk, previously untreated advanced renal cell carcinoma. More Information. April 16, 2018
- FDA approved everolimus tablets for oral suspension (Afinitor Disperz, Novartis Pharmaceuticals Corp.) for the adjunctive treatment of adult and pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures. Everolimus is also approved for two other manifestations of TSC: TSC-associated subependymal giant cell astrocytoma (SEGA) and TSC-associated renal angiomyolipoma. More Information. April 10, 2018
- FDA approved rucaparib for maintenance treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer. More Information. April 6, 2018
- FDA granted accelerated approval to blinatumomab (Blincyto, Amgen Inc.) for the treatment of adult and pediatric patients with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. More Information. March 29, 2018
- FDA approved nilotinib (TASIGNA, Novartis Pharmaceuticals Corporation) for pediatric patients 1 year of age or older with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. More Information. March 22, 2018
- FDA approved brentuximab vedotin (Adcetris, Seattle Genetics, Inc.) to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy. More Information. March 20, 2018
- FDA approved abemaciclib (VERZENIO, Eli Lilly and Company) in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. More Information. February 26, 2018
- FDA approved durvalumab (Imfinzi, AstraZeneca Inc.) for patients with unresectable stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. More Information. February 16, 2018
- FDA approves apalutamide for non-metastatic castration-resistant prostate cancer. More Information. February 14, 2018
- FDA approved abiraterone acetate (Zytiga, Janssen Biotech Inc.) tablets in combination with prednisone for metastatic high-risk castration-sensitive prostate cancer (CSPC). More Information. February 7, 2018
- FDA approved lutetium Lu 177 dotatate (LUTATHERA, Advanced Accelerator Applications USA, Inc.) a radiolabeled somatostatin analog, for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. More Information. January 26, 2018
- FDA granted approval to afatinib (Gilotrif, Boehringer Ingelheim Pharmaceutical, Inc.) for a broadened indication in first-line treatment of patients with metastatic non-small cell lung

cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. More Information. January 12, 2018

- FDA granted regular approval to olaparib tablets (Lynparza, AstraZeneca Pharmaceuticals LP), a poly (ADP-ribose) polymerase (PARP) inhibitor, for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative metastatic breast cancer who have been treated with chemotherapy either in the neoadjuvant, adjuvant, or metastatic setting. More Information. January 12, 2018