Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Washington Pharmacy Advisory Committee Meeting

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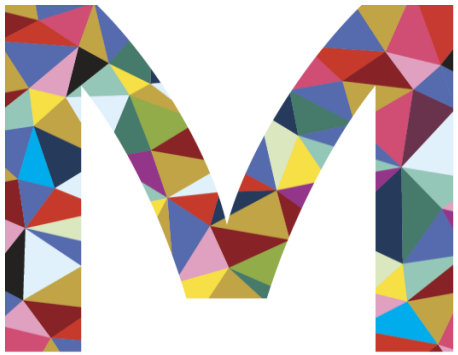
Agenda Topics

- Overview of Disease State
- Indications
- Dosage & Formulations
- Guideline Updates



Magellan Rx MANAGEMENT℠

Magellan Medicaid Administration

Oncology Agents

Overview of Disease State – Oncology, Oral

- ANDROGEN BIOSYNTHESIS INHIBITORS – ORAL– **NO UPDATES**
  - Yonsa
  - Abiraterone Acetate
  - Zytiga
- ANTIANDROGENS – ORAL
  - **Erleada**
  - Bicalutamide
  - Casodex
  - Nubeqa
  - **Xtandi**
  - Flutamide
  - Nilandron
  - Nilutamide
- **ANTINEOPLASTICS - MISC COMBINATIONS – ORAL**
  - **Kisqali Femara**
  - Lonsurf
- **BRAF KINASE INHIBITORS – ORAL**
  - Tafinlar
  - **Braftovi**
  - Zelboraf
- **CYCLIN DEPENDENT KINASES (CDK) INHIBITORS – ORAL**
  - Verzenio
  - **Ibrance**
  - Kisqali
- **FGFR KINASE INHIBITORS – ORAL– NO UPDATES**
  - Balversa
  - Pemazyre
- **HEDGEHOG PATHWAY INHIBITORS – ORAL– NO UPDATES**
  - Daurismo
  - Odomzo
  - Erivedge
- **MEK INHIBITORS – ORAL – NO UPDATES**
  - Mektovi
  - Cotellic
  - Koseluigo
- **MTOR KINASE INHIBITORS – ORAL**
  - **Everolimus**
  - Afinitor
  - Afinitor Disperz
- **MULTIKINASE INHIBITORS – ORAL – NO UPDATES**
  - Rydapt
  - Stivarga
  - Nexavar
  - Sutent
- **POLY (ADP-RIBOSE) POLYMERASE (PARP) INHIBITORS – ORAL**
  - **Zejula**
  - **Lynparza**
  - **Rubraca**
  - Talzenna
- **RETINOIDS – ORAL– NO UPDATES**
  - Tretinoin
- **TOPOISOMERASE INHIBITORS - ORAL– NO UPDATES**
  - Hycamtin
- **TROPOMYOSIN RECEPTOR KINASE INHIBITORS – ORAL– NO UPDATES**
  - Rozlytrek
  - Vitrakvi

Oncology, Oral- Hematological

- apalutamide (Erleada)
  - **September 2019: FDA approved expanded indication for treatment of metastatic castration-sensitive prostate cancer (mCSPC); previously only approved for non-metastatic castration-resistant prostate cancer**
  - **Indication**
    - **Metastatic castration-sensitive prostate cancer**
    - Non-metastatic castration-resistant prostate cancer
  - **Warnings and Precautions**
    - Ischemic cardiovascular events occurred in patients receiving treatment; monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors
    - Fractures occurred in patients receiving treatment; evaluate patients for fracture risk and treat patients with bone-targeted agents according to established guidelines
    - Falls occurred in patients receiving treatment with increased incidence in the elderly
    - Seizure occurred in 0.4% of patients receiving treatment; permanently discontinue ERLEADA in patients who develop a seizure during treatment
    - Embryo-Fetal Toxicity: Erleada can cause fetal harm; advise males with female partners of reproductive potential to use effective contraception
  - **Dosage**
    - 240 mg (four 60 mg tablets) administered orally once daily
    - Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy
  - **Availability**
    - Tablets: 60 mg

Oncology, Oral- Hematological

- enzalutamide (Xtandi)
  - **December 2019: FDA approved expanded indication for the treatment of patients with metastatic castration-sensitive prostate cancer; already indicated for the treatment of patients with castration-resistant prostate cancer**
  - **Indication**
    - Patients with castration-resistant prostate cancer
    - **Patients with metastatic castration-sensitive prostate cancer**
  - **Warnings and Precautions**
    - Ischemic cardiovascular events occurred in patients receiving treatment; monitor for signs and symptoms of ischemic heart disease. Discontinue for Grade 3-4 events
    - Fractures occurred in patients receiving treatment; evaluate patients for fracture risk and treat patients with bone-targeted agents according to established guidelines
    - Falls occurred in patients receiving treatment with increased incidence in the elderly
    - Seizure occurred in 0.5% of patients receiving treatment; permanently discontinue ERLEADA in patients who develop a seizure during treatment
    - Embryo-Fetal Toxicity: Xtandi can cause fetal harm; advise males with female partners of reproductive potential to use effective contraception
  - **Dosage**
    - 160 mg (four 40 mg tablets) administered orally once daily
    - Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy
  - **Availability**
    - Capsule: 40 mg

Oncology, Oral- Hematological

- ribociclib and letrozole (Kisqali Femara Co-Pack)
  - **September 2019: FDA approved expanded indication for the initial endocrine-based therapy for the treatment of pre/perimenopausal or postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer. Previously, this was approved in postmenopausal women only**
  - **Indication**
    - **A co-packaged product containing ribociclib, a kinase inhibitor, and letrozole, an aromatase inhibitor, is indicated as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer**
  - **Warnings and Precautions**
    - QT interval prolongation: Monitor ECGs and electrolytes prior to initiation of treatment; repeat ECGs at approximately Day 14 of the first cycle and at the beginning of the second cycle, and as clinically indicated
    - Hepatobiliary toxicity: Increases in serum transaminase levels have been observed; perform Liver Function Tests (LFTs) before initiating treatment and every 2 weeks for the first 2 cycles, at the beginning of each subsequent 4 cycles, and as clinically indicated
    - Neutropenia: Perform Complete Blood Count (CBC) before initiating therapy. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each subsequent 4 cycles, and as clinically indicated
    - Embryo-Fetal toxicity: Can cause fetal harm when administered to pregnant women; advise women of child-bearing potential of the potential risk to a fetus and to use effective contraception during therapy
  - **Dosage**
    - Kisqali recommended starting dose: 600 mg orally (three 200 mg tablets) taken once daily for 21 consecutive days followed by 7 days off treatment
    - Femara: 2.5 mg (one tablet) continuously for a 28-day cycle
  - **Availability**
    - Tablets: Kisqali 200 mg and Femara 2.5 mg

Oncology, Oral- Hematological

- encorafenib (Braftovi)
  - **April 2020: FDA approved a new indication, in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy. It is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC**
  - **April 2020: FDA approved a companion diagnostic, the therascreen BRAF V600E RGQ PCR Kit, for Braftovi's approved indication**
  - **Indications**
    - In combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test
    - **In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy**
  - **Warnings and Precautions**
    - QT interval prolongation: Monitor electrolytes before and during treatment. Correct electrolyte abnormalities and control for cardiac risk factors for QT prolongation
    - Embryo-Fetal toxicity: Can cause fetal harm when administered to pregnant women; advise women of child-bearing potential of the potential risk to a fetus and to use effective non-hormonal contraception during therapy
    - New Primary Malignancies, cutaneous and non-cutaneous: Can occur; monitor for malignancies and perform dermatologic evaluations prior to, while on therapy, and following discontinuation of treatment
    - Tumor Promotion in BRAF Wild-Type Tumors: Increased cell proliferation can occur with BRAF inhibitors
    - Hemorrhage: Major hemorrhagic events can occur
  - **Dosage**
    - Dosage is stratified by indication – can be found in TCR or Package Insert
  - **Availability**
    - Capsules: 75 mg

Oncology, Oral- Hematological

- palbociclib (Ibrance)
  - **November 2019: FDA approved new tablet formulations**
  - **Indications**
    - A kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
      - An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or
      - Fulvestrant in patients with disease progression following endocrine therapy
  - **Warnings and Precautions**
    - Neutropenia: Perform Complete Blood Count (CBC) at the beginning of each cycle, as well as on Day 15 of the first 2 cycles, and as clinically indicated
    - Embryo-Fetal toxicity: Can cause fetal harm when administered to pregnant women; advise women of child-bearing potential of the potential risk to a fetus and to use effective contraception during therapy
    - Interstitial Lung Disease (ILD)/Pneumonitis: Severe and fatal cases of ILD/pneumonitis have been reported; monitor for pulmonary symptoms of ILD/pneumonitis
  - **Dosage**
    - Recommended starting dose: 125 mg once daily taken with food for 21 days followed by 7 days off treatment
  - **Availability**
    - **Tablets: 125 mg, 100 mg, and 75 mg**
    - Capsules: 125 mg, 100 mg, and 75 mg

Oncology, Oral- Hematological

- everolimus (Afinitor)
  - **January 2020: FDA approved first generics for Afinitor from Par (2.5 mg, 5 mg, 7.5 mg) and Teva (2.5 mg, 5 mg, 7.5 mg, 10 mg). Par/Endo announced they have launched their products**
  - **Indications**
    - A kinase inhibitor indicated for the treatment of:
      - Postmenopausal women with advanced hormone receptor-positive, HER2- negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole
      - Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. Limitations of Use: AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors
      - Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib
      - Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery
  - **Warnings and Precautions**
    - Black Box Warning: Only physicians experienced in immunosuppressive therapy and management of transplant patients should prescribe everolimus. Immunosuppression increases susceptibility to infection and risk of malignancies, such as lymphoma and skin cancer. Increased risk of kidney arterial and venous thrombosis resulting in graft loss was reported within the first 30 days posttransplantation
    - To avoid nephrotoxicity, reduce doses of cyclosporine when used in combination with everolimus and monitor cyclosporine and everolimus whole blood trough concentrations. Do not use in heart transplantation; serious infections and increased mortality within the first 3 months posttransplant was observed
  - **Dosage**
    - Dosage is stratified by indication – can be found in TCR or Package Insert
  - **Availability**
    - Tablets: 2.5 mg, 5 mg, 7.5 mg, and 10 mg tablets

Oncology, Oral- Hematological

- niraparib (Zejula)
  - **May 2020: FDA approved new indication for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy; previously indicated only for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy**
  - **Indications**
    - Poly(ADP-ribose) polymerase (PARP) inhibitor indicated:
      - For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy
      - **For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy**
      - For the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
        - A deleterious or suspected deleterious BRCA mutation, or
        - Genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy
  - **Warnings and Precautions**
    - Embryo-Fetal toxicity: Can cause fetal harm when administered to pregnant women; advise women of child-bearing potential of the potential risk to a fetus and to use effective contraception during therapy
  - **Dosage**
    - Dosage is stratified by indication – can be found in TCR or Package Insert
  - **Availability**
    - Capsules: 100 mg

Oncology, Oral- Hematological

- olaparib (Lynparza)
  - **May 2020: FDA approved a new indication for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen**
  - **May 2020: FDA approved in combination with bevacizumab for the maintenance treatment of adults with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: (1) a deleterious or suspected deleterious BRCA mutation, and/or (2) genomic instability (select patients for therapy based on an FDA-approved companion diagnostic)**
  - **May 2020: FDA approved a new indication for treatment of adults with deleterious or suspected deleterious germline or somatic homologous recombinant repair (HRR) gene-mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone**
  - **Indications**
    - Poly(ADP-ribose) polymerase (PARP) inhibitor indicated for Ovarian cancer, Breast cancer, Pancreatic cancer, and Prostate cancer
    - In-depth information can be found in TCRs and Package Insert
  - **Warnings and Precautions**
    - Embryo-Fetal toxicity: Can cause fetal harm when administered to pregnant women; advise women of child-bearing potential of the potential risk to a fetus and to use effective contraception during therapy
    - Venous thromboembolic events including pulmonary embolism occurred in 7% of patients with mCRPC. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate
  - **Dosage**
    - 300 mg taken orally twice daily with or without food
    - Patients receiving Lynparza for metastatic castration-resistant prostate cancer (mCRPC) should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy
  - **Availability**
    - Tablets: 150 and 100 mg

Oncology, Oral- Hematological

- rucaparib (Rubraca)
  - **May 2020: FDA approved new indication for the treatment adults with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy; FDA-approved test to detect BRCA1/BRCA2 mutations in patients with mCRPC is not currently available**
  - **Indications**
    - Ovarian cancer
      - For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
      - For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies
    - Prostate cancer
      - **For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy**
      - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials
  - **Warnings and Precautions**
    - Embryo-Fetal toxicity: Can cause fetal harm when administered to pregnant women; advise women of child-bearing potential of the potential risk to a fetus and to use effective contraception during therapy
    - Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to treatment, and some cases were fatal. Monitor patients for hematological toxicity at baseline and monthly. Discontinue if MDS/AML is confirmed
  - **Dosage**
    - 600 mg orally twice daily
  - **Availability**
    - Tablets: 200, 250, and 300 mg

Overview of Disease State – Oncology, Oral

- **TYROSINE KINASE INHIBITORS– ORAL**
  - **Calquence**
  - Gilotrif
  - Alecensa
  - **Inlyta**
  - **Ayvakit**
  - **Alunbrig**
  - Bosulif
  - Cabometyx
  - Cometriq
  - Zykadia
  - **Tabrecta**
  - Vizimpro
  - Sprycel
  - Erlotinib Hydrochloride
  - Tarceva
  - Iressa
  - Xospata
  - Imbruvica

- **TYROSINE KINASE INHIBITORS– ORAL**
  - Imatinib Mesylate
  - Gleevec
  - Tykerb
  - **Lenvima**
  - Lobrena
  - **Nerlynx**
  - Tasigna
  - Tagrisso
  - Votrient
  - **Turalio**
  - Iclusig
  - **Qinlock**
  - Retevmo
  - **Tukysa**
  - Caprelsa
  - **Brukinsa**

Oncology, Oral- Hematological

- acalabrutinib (Calquence)
  - **November 2019: FDA approved a new indication for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); it was already approved for adults with Mantle cell lymphoma (MCL) who have received at least one prior therapy**
  - **Indications**
    - A kinase inhibitor indicated for the treatment of adult patients with:
      - Mantle cell lymphoma (MCL) who have received at least one prior therapy
      - This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials
      - **Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)**
  - **Warnings and Precautions**
    - Serious and Opportunistic Infections: Monitor for signs and symptoms of infection and treat promptly
    - Hemorrhage: Monitor for bleeding and manage appropriately
    - Cytopenias: Monitor complete blood counts regularly
    - Second Primary Malignancies: Other malignancies have occurred, including skin cancers and other solid tumors. Advise patients to use sun protection
    - Atrial Fibrillation and Flutter: Monitor for symptoms of arrhythmias and manage
  - **Dosage**
    - 100 mg orally approximately every 12 hours
  - **Availability**
    - Capsules: 100 mg

Oncology, Oral- Hematological

- axitinib (Inlyta)
  - **June 2020: FDA approved a new indication in combination with avelumab or pembrolizumab for the first-line treatment of patients with advanced renal cell carcinoma (RCC). Previously approved as a single agent, for the treatment of advanced RCC after failure of 1 prior systemic therapy**
  - **Indications**
    - A kinase inhibitor indicated for the treatment of adult patients with:
      - **In combination with avelumab, for the first-line treatment of patients with advanced renal cell carcinoma**
      - **In combination with pembrolizumab, for the first-line treatment of patients with advanced RCC**
      - As a single agent, for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy
  - **Warnings and Precautions**
    - Hypertension and Hypertensive Crisis: Hypertension including hypertensive crisis has been observed. Blood pressure should be well-controlled prior to initiating treatment. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the dose
    - Arterial and Venous Thromboembolic Events: Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk for these events
    - Cardiac Failure: Cardiac failure has been observed and can be fatal. Monitor for signs or symptoms of cardiac failure throughout treatment
  - **Dosage**
    - 5 mg orally twice daily with avelumab 800 mg every 2 weeks
    - 5 mg orally twice daily with pembrolizumab 200 mg every 3 weeks or 400 mg every 6 weeks
    - As a single agent the starting dose is 5 mg orally twice daily
  - **Availability**
    - Tablets: 1 and 5 mg

Oncology, Oral- Hematological

- avapritinib (Ayvakit)
  - **January 2020: FDA approved a new drug indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations**
  - **Indications**
    - **A kinase inhibitor indicated for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations**
  - **Warnings and Precautions**
    - **Intracranial Hemorrhage: Withhold treatment for Grade 1 or 2 reactions until resolution and then resume at a reduced dose. Permanently discontinue for recurrent Grade 1 or 2 reactions or first occurrence of Grade 3 or 4 reactions**
    - **Central Nervous System (CNS) Effects: CNS adverse reactions include cognitive impairment, dizziness, sleep disorders, mood disorders, speech disorders, and hallucinations. Depending on the severity, continue AYVAKIT at same dose, withhold and then resume at same or reduced dose upon improvement, or permanently discontinue**
    - **Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception**
  - **Dosage**
    - **300 mg orally once daily**
  - **Availability**
    - **Tablets: 100, 200, and 300 mg**

Oncology, Oral- Hematological

- brigatinib (Alunbrig)
  - **May 2020: FDA approved a new drug indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test; patients should be selected for treatment of metastatic NSCLC based on the presence of ALK positivity in tumor specimens**
  - **Indications**
    - **A kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test**
  - **Warnings and Precautions**
    - Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening respiratory symptoms, particularly during the first week of treatment. Withhold treatment for new or worsening respiratory symptoms and promptly evaluate for ILD/pneumonitis
    - Hypertension: Monitor blood pressure after 2 weeks and then at least monthly during treatment. For severe hypertension, withhold treatment, then dose reduce or permanently discontinue
    - Bradycardia: Monitor heart rate and blood pressure regularly during treatment. If symptomatic, withhold treatment, then dose reduce or permanently discontinue
    - Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use a non-hormonal method of effective contraception
  - **Dosage**
    - 90 mg orally once daily for the first 7 days; then increase to 180 mg orally once daily
  - **Availability**
    - Tablets: 30, 90, 180 mg

Oncology, Oral- Hematological

- capmatinib (Tabrecta)
  - **May 2020: FDA approved Tabrecta, a kinase inhibitor, indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test; the FDA also approved the FoundationOne CDx assay as a companion diagnostic test**
  - **Indications**
    - **A kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test**
  - **Warnings and Precautions**
    - **Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening respiratory symptoms, particularly during the first week of treatment. Withhold treatment for new or worsening respiratory symptoms and promptly evaluate for ILD/pneumonitis**
    - **Hepatotoxicity: Monitor liver function tests. Withhold, dose reduce, or permanently discontinue treatment based on severity**
    - **Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use a non-hormonal method of effective contraception**
  - **Dosage**
    - **90 mg orally once daily for the first 7 days; then increase to 180 mg orally once daily**
  - **Availability**
    - **Tablets: 150 and 200 mg**

Oncology, Oral- Hematological

- lenvatinib (Lenvima)
  - **September 2019: FDA approved expanded indication for use in combination with pembrolizumab, for treatment of advanced endometrial carcinoma that is not MSI-H or dMMR, in patients with disease progression after prior systemic therapy and are not candidates for curative surgery or radiation**
  - **Indications**
    - For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC)
    - In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior antiangiogenic therapy
    - For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
    - **In combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial**
  - **Dosage**
    - DTC: The recommended dosage is 24 mg orally once daily.
    - RCC: The recommended dosage is 18 mg orally once daily with everolimus 5 mg orally once daily
    - HCC: The recommended dosage is based on actual body weight:
      - 12 mg orally once daily for patients greater than or equal to 60 kg
      - 8 mg orally once daily for patients less than 60 kg
    - Endometrial Carcinoma: The recommended dosage is 20 mg orally once daily with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks
  - **Availability**
    - **Capsules: 4 and 10 mg**

Oncology, Oral- Hematological

- neratinib (Nerlynx)
  - **February 2020: FDA approved for use in combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting; already indicated as a single agent, for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy**
  - **Indications**
    - As a single agent, for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumabbased therapy
    - **In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting**
  - **Warnings and Precautions**
    - Hepatotoxicity: Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold treatment in patients experiencing Grade 3 liver abnormalities and permanently discontinue treatment in patients experiencing Grade 4 liver abnormalities
    - Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception
  - **Dosage**
    - Extended Adjuvant Treatment of Early Stage Breast Cancer: 240 mg (6 tablets) given orally once daily, with food, continuously until disease recurrence for up to one year
    - Advanced or metastatic breast cancer: 240 mg (6 tablets) given orally once daily with food on Days 1-21 of a 21-day cycle plus capecitabine (750 mg/m2 given orally twice daily) on Days 1-14 of a 21-day cycle until disease progression or unacceptable toxicities
  - **Availability**
    - Tablets: 40 mg

Oncology, Oral- Hematological

- pexidartinib (Turalio)
  - August 2019: FDA approved Turalio for the treatment of adults with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery
  - Indications
    - Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery
  - Warnings and Precautions
    - Embryo-Fetal Toxicity: May cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use an effective non-hormonal method of contraception
    - Black Box Warning: Can cause serious and potentially fatal liver injury
      - Monitor liver tests prior to initiation of treatment and at specified intervals during treatment
      - Withhold dose and reduce or permanently discontinue pexidartinib based on severity of hepatotoxicity
      - Turalio is available only through a restricted program call the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program
  - Dosage
    - Recommended Dosage: 400 mg orally twice daily
  - Availability
    - Capsules: 200 mg

Oncology, Oral- Hematological

- ripretinib (Qinlock)
  - **May 2020: FDA approved Qinlock the treatment of adults with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with ≥ 3 kinase inhibitors, including imatinib**
  - **Indications**
    - **A kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib**
  - **Warnings and Precautions**
    - **Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception**
    - **Risk of Impaired Wound Healing: Withhold treatment for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks after major surgery and until adequate wound healing. The safety of resumption of Qinlock after resolution of wound healing complications has not been established**
    - **New Primary Cutaneous Malignancies: Perform dermatologic evaluations when initiating Qinlock and routinely during treatment**
    - **Cardiac Dysfunction: Assess ejection fraction by echocardiogram or MUGA scan prior to initiating treatment and during treatment, as clinically indicated. Permanently discontinue for Grade 3 or 4 left ventricular systolic dysfunction**
  - **Dosage**
    - **Recommended Dosage: 150 mg orally once daily with or without food**
  - **Availability**
    - **Tablets: 50 mg**

Oncology, Oral- Hematological

- tucatinib (Tukysa)
  - April 2020: FDA approved Tukysa for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received ≥ 1 prior anti-HER2-based regimen(s) in the metastatic setting
  - Indications
    - A kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting
  - Warnings and Precautions
    - Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception
    - Hepatotoxicity: Severe hepatotoxicity has been reported. Monitor ALT, AST and bilirubin prior to starting Tukysa, every 3 weeks during treatment and as clinically indicated
    - Diarrhea: Severe diarrhea, including dehydration, acute kidney injury, and death, has been reported. Administer antidiarrheal treatment as clinically indicated
  - Dosage
    - Recommended dosage: 300 mg taken orally twice daily with or without food
    - For patients with severe hepatic impairment, the recommended dosage is 200 mg orally twice daily
  - Availability
    - Tablets: 50 and 150 mg

Oncology, Oral- Hematological

- zanubrutinib (Brukinsa)
  - November 2019: FDA approved Brukinsa for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
  - Indications
    - A kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
    - This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial
  - Warnings and Precautions
    - Embryo-Fetal Toxicity: Can cause fetal harm. Advise women of the potential risk to a fetus and to avoid pregnancy
    - Hemorrhage: Monitor for bleeding and manage appropriately
    - Infections: Monitor patients for signs and symptoms of infection, including opportunistic infections, and treat as needed
    - Cytopenias: Monitor complete blood counts during treatment
    - Second Primary Malignancies: Other malignancies have occurred in patients including skin cancers. Advise patients to use sun protection
    - Cardiac Arrhythmias: Monitor for atrial fibrillation and atrial flutter and manage appropriately
  - Dosage
    - Recommended dose: 160 mg orally twice daily or 320 mg orally once daily
    - Reduce dose in patients with severe hepatic impairment
  - Availability
    - Capsules: 80 mg

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Ophthalmic Agents: Glaucoma Agents

Disease State Description - Ophthalmic, Glaucoma Agents

- Approximately 2.7 million people in the United States (U.S.) suffer from glaucoma
  - It is the second most common cause of permanent blindness in the U.S. and the most common cause of blindness among African Americans and Hispanics
  - Risk factors for the development of glaucoma include elevated IOP, advancing age (> 40 years), family history of glaucoma, and African American or Hispanic descent
- Increased IOP is common in glaucoma and is believed to contribute to the damage to the optic nerve, which can lead to loss of visual sensitivity and field
  - However, some patients with glaucoma have normal IOP, and many patients with elevated IOP do not have glaucoma
  - IOP alone is no longer considered a diagnostic criterion for glaucoma
- Two major types of glaucoma have been identified: open-angle and closed-angle
  - In open-angle glaucoma, there is reduced flow through the trabecular meshwork
    - Open-angle glaucoma accounts for the majority of cases
  - In closed-angle glaucoma, the iris is pushed forward against the trabecular meshwork, blocking fluid from escaping
- Reduction of IOP may be achieved either by decreasing the rate of production of aqueous humor or increasing the rate of outflow of aqueous humor from the anterior chamber of the eye
- Topical ocular hypotensive agents can delay or prevent the development of primary open-angle glaucoma in some patients

American Academy of Ophthalmology, 2017

Ophthalmic, Glaucoma Agents

- bimatoprost (Durysta)
  - **March 2020: FDA approved a new formulation for Durysta, a bimatoprost implant, indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT)**
  - **Indication**
    - Reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT)
  - **Warnings and Precautions**
    - Endothelial cell loss: Due to possible corneal endothelial cell loss, administration of Durysta should be limited to a single implant per eye without retreatment
    - Corneal Adverse Reactions: Durysta has been associated with corneal adverse reactions and risks are increased with multiple implants. Use caution in patients with limited corneal endothelial cell reserve
    - Iridocorneal Angle: DURYSTA should be used with caution in patients with narrow angles or anatomical angle obstruction
  - **Dosage**
    - For ophthalmic intracameral administration
    - The intracameral administration should be carried out under standard aseptic conditions
  - **Availability**
    - Intracameral implant containing bimatoprost 10 mcg, in the drug delivery system

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Ophthalmic Agents: Immunomodulators

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Respiratory Agents: Pulmonary Fibrosing Agents

Overview of Disease State – Idiopathic Pulmonary Fibrosis

- Idiopathic pulmonary fibrosis (IPF) is a chronic, progressing lung disease occurring primarily in middle-aged to older adults
- It is characterized by progressive fibrosis resulting in decreased ventilation and gas exchange
- In the United Stated (US), it is estimated that IPF affects about 132,000 people, with approximately 50,000 new cases being diagnosed and over 30,000 deaths each year
  - Researchers expect this number to rise, due to improvement in accurate diagnosis and longer life-expectancy as disease understanding and management increase
- While the cause of IPF is unknown, a primary theory of pathogenesis is an inciting factor in a susceptible patient that may cause the initial alveolar damage, provoking a response ultimately leading to fibrosis
- Potential risk factors for IPF include smoking, gastroesophageal reflux disease (GERD), diabetes, and viral infections, such as hepatitis C
- Possible causes of pulmonary fibrosis include environmental toxins, medications, and genetic predisposition
- Most commonly, death is due to respiratory failure, but other causes include pulmonary hypertension, heart failure, pulmonary embolism, pneumonia, and lung cancer

Idiopathic Pulmonary Fibrosis

- nintedanib esylate (Ofev)
  - **September 2019: FDA approved expanded indication to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)**
  - **March 2020: FDA approved a new indication for the treatment for chronic fibrosing interstitial lung diseases with a progressive phenotype**
  - **Indication**
    - Treatment of idiopathic pulmonary fibrosis (IPF)
    - **Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype**
    - **Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)**
  - **Warnings and Precautions**
    - Hepatic impairment: OFEV is not recommended for use in patients with moderate or severe hepatic impairment
    - Elevated liver enzymes and drug-induced liver injury: ALT, AST, and bilirubin elevations have occurred with OFEV, including cases of druginduced liver injury
    - Prior to treatment initiation, conduct liver function tests in all patients and a pregnancy test in females of reproductive potential
  - **Dosage**
    - 150 mg twice daily approximately 12 hours apart (Max dosage of 300 mg/day)
    - Prior to treatment initiation, conduct liver function tests in all patients and a pregnancy test in females of reproductive potential
  - **Availability**
    - Capsules: 150 mg and 100 mg

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Smoking Cessation