

| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
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| Original Development Date: | August 6, 2012 |
| Revision Date: | December 6, 2012; December 21, 2012; December 27, 2012; January 14, 2013; January 18, 2013; March 18, 2013; August, 1, 2013; October 8, 2013; November 6, 2013; December 18, 2013; January 14, 2014; July 10, 2014; August 8, 2014; June 8, 2015; October 14, 2015; February 4, 2016; March 4, 2016; May 17, 2016; February 14, 2017; March 14, 2017; March 21, 2017; July 11, 2017; August 7, 2017; November 3, 2017; December 21, 2017; January 17, 2018; February 12, 2018; March 14, 2018; March 28, 2018; April 2, 2018; April 24, 2018; April 24, 2018; May 9, 2018; June 5, 2018; June 18, 2018; July 27, 2018; August 28, 2018; October 29, 2018; December 27, 2018; February 27, 2019; March 27, 2019; June 14, 2019; August 19, 2019; December 2, 2019; January 29, 2020; March 4, 2020; May 27, 2020; June 29, 2020; August 6, 2020; August 20, 2020; September 25, 2020; October 30, 2020; July 13, 2021; August 23, 2021; September 17, 2021; October 16, 2021; December 8, 2021; March 11, 2022; June 17, 2022; August 31, 2022; September 19, 2022; November 15, 2022; January 27, 2023; May 02, 2023; May 11, 2023, July 18, 2023, October 2, 2023; January 24, 2024; February 28, 2024, July 1, 2024, August 27, 2024, November 13, 2024 |

ORAL ONCOLOGY CRITERIA

<u>LENGTH OF AUTHORIZATION</u>: Varies; Maximum of one year

REVIEW CRITERIA:

| Drug Name | Indication & Dosage | Age Limit | Quantity per day | Quantity Limit |
|--|--|------------------|--|--|
| AFINITOR® (everolimus) AFINITOR DISPERZ® (everolimus) | Postmenopausal women with advanced hormone receptor-positive, HER2- negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole; progressive neuroendocrine tumors of pancreatic origin; advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib; renal angiomyolipoma and tuberous sclerosis complex; progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic: 10 mg by mouth daily. Subependymal giant cell astrocytoma associated with tuberous sclerosis complex: 4.5 mg/m² by mouth once daily; adjust dose to attain trough concentrations of 5-15 ng/mL. | minimum age = 1 | AFINITOR TABLETS: 1 (10mg) 1 (2.5mg, 5mg, 7.5mg) AFINITOR DISPERZ: 2 (2mg, 5mg) 3 (3mg) | 30 per 30 days 60 per 30 days (2, 5 mg) 90 per 30 days (3mg) |
| AKEEGA® (niraparib and abiraterone acetate) | Indicated for use in combination with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), based on an FDA-approved test. 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 10 mg prednisone daily until disease progression or unacceptable toxicity. | minimum age – 18 | 2 (50 mg/500 mg) 2 (100 mg/500 mg) | 60 per 30 days |
| ALECENSA® (alectinib) | Anaplastic lymphoma kinase positive metastatic non-small cell lung cancer as detected by an FDA-approved test. | minimum age – 18 | 8 (150mg) | 240 per 30 days |



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| | 600 mg by mouth twice daily. | | | |
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| ALUNBRIG™ (brigatinib) | Adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. 90 mg by mouth once daily for the first 7 days; then increase to 180 mg by mouth once daily. | minimum age =18 | 2 (30mg) 2 (90mg) 1 (180mg) | 60 per 30 days (30mg) 30 per 30 days (90mg) 30 per 30 days (180mg) |
| AUGTYRO™ (repotrectinib) | Adult patients diagnosed with locally advanced or metastatic <i>ROS1</i> -positive nonsmall cell lung cancer (NSCLC) as determined by an FDA approved test. 160 mg by mouth once daily for 14 days, then increase to 160 mg by mouth twice daily. | minimum age =18 | 8 (40mg) | 240 per 30 days |
| AYVAKIT [™] (avapritinib) | Treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Treatment of adults with Advanced Systemic Mastocytosis (AdvSM) including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL) with platelet counts > 50 x 10°/L. GIST: 300mg once daily AdvSM: 200mg once daily | minimum age =18 | (1) 25mg (1) 50mg (1) 100mg (1) 200mg (1) 300mg | 30 per 30 days |
| BALVERSA™ (erdafitinib) | Adult patients with locally advanced or metastatic urothelial carcinoma that is susceptible to FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. 8mg by mouth daily with a dose increase to 9mg by mouth once daily based on serum phosphate levels and tolerability at 14-21 days. | minimum age =18 | 1 (3mg) 2 (4mg) 1 (5mg) | 30 per 30 days (3mg and 5mg) 60 per 30 days (4mg) |



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| BOSULIF® (bosutinib) BRAFTOVI™ (encorafenib) | Newly-diagnosed chronic phase Ph+ CML: 400 mg by mouth once daily Chronic, accelerated, or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML) with resistance, or intolerance to prior therapy: 500-600 mg by mouth daily. Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test in | minimum age = 18 minimum age = 18 | 1 (500mg) 1 (400mg) 1 (100mg) 6 (75mg) | 30 per 30 days 180 per 30 days (75mg) |
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| | combination with binimetinib. 450 mg by mouth once daily Metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy in combination with cetuximab. 300 mg by mouth orally once daily. | | | |
| BRUKINSA® (zanubrutini) | Adult patients with mantle cell lymphoma who have received at least one prior therapy. Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen. Waldenström's macroglobulinemia. 160mg by mouth twice daily or 320mg once daily. | minimum age = 18 | 4 (80mg) | 120 per 30 days |
| CABOMETYX® (cabozantinib) | Single agent for advanced renal cell carcinoma (RCC). In combination with nivolumab, as a first-line treatment in advanced RCC. Patients with hepatocellular carcinoma who have been previously treated with sorafenib. Adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior | minimum age = 18 | 1 (60mg) 1 (40mg) 1 (20mg) | 30 per 30 days |



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| | VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. Single agent: 60mg by mouth once daily; 40 mg orally, once daily, in pediatric patients with BSA less than 1.2 m ² . In combination with nivolumab: 40mg by mouth once daily. | | | |
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| CALQUENCE® (acalabrutinib) | Mantle cell lymphoma (MCL) who have received at least one prior therapy. Chronic lymphocytic leukemia or small lymphocytic lymphoma. 100mg by mouth every 12 hours until disease progression or unacceptable toxicity occurs. | minimum age = 18 | 2 (100mg) | 60 per 30 days |
| CAPRELSA® (vandetanib) | Symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. 300mg by mouth once daily. | minimum age = 18 | 2 (100mg) 1 (300mg) | 60 per 30 days |
| COMETRIQ® (cabozantinib) | Progressive, metastatic medullary thyroid cancer: 140 mg by mouth daily. | minimum age =18 | N/A | 60 mg carton – 84 per 30 days 100 mg carton – 56 per 30 days 140 mg carton – 112 per 30 days |
| COPIKTRA™ (duvelisib) | Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior systemic therapies. 25mg by mouth twice daily. | minimum age =18 | 2 (25mg) 2 (15mg) | 60 per 30 days |
| COTELLIC® (cobimetinib) | Metastatic or unresectable melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to initiation of therapy. Single agent for the treatment of adult patients with histiocytic neoplasms. 60mg by mouth once daily for 21 days and 7 days off. | minimum age = 18 | 3 (20mg) | 63 every 30 days |



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| DATIDISMO TM (-la-da-sh) | NT 1 1' 1 . 1 '11 1 ' | | 1 (100) | 20 20 1 (100) |
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| DAURISMO™ (glasdegib) | Newly diagnosed acute myeloid leukemia who are ≥ 75 years old; or who have comorbidities that preclude use of intensive induction chemotherapy. 100mg by mouth once daily on days 1-28 of the 28 day cycle. | minimum age = 18 | 1 (100mg) 3 (25mg) | 30 every 30 days (100mg) 90 every 30 days (25mg) |
| EMCYT® (estramustine) | Palliative treatment of patients with metastatic and/or progressive carcinoma of the prostate: 10-16 mg/kg/day by mouth divided three times daily to four times daily. | minimum age = 18 | N/A | N/A |
| ERIVEDGE® (vismodegib) | Basal cell carcinoma: 150 mg by mouth daily. | minimum age = 18 | 1 (150mg) | 30 per 30 days |
| ERLEADA®(apalutamide) | Non-metastatic castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. 240mg by mouth once daily. | minimum age = 18 | 4 (60mg) 1 (240 mg) | 120 per 30 days |
| EXKIVITY™ (mobocertinib) | Locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. 160 mg orally once daily. | minimum age = 18 | 4 (40mg) | 120 per 30 days |
| FARESTON® (toremifene) | Metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors: 60 mg by mouth daily. | minimum age = 18 | 1 (60mg) | 30 per 30 days |
| FOTIVDA® (tivozanib) | Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. 1.34mg by mouth once daily for 21 days on treatment followed by 7 days off (28- day cycle) | minimum age = 18 | 1 (1.34mg, 0.89mg) | 21 per 28 days |
| FRUZAQLA TM (fruquintinib) | For the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type | minimum age = 18 | 4 (1mg) 1 (5mg) | 84 per 28 days (1mg) 21 per 28 days (5mg) |



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| | and medically appropriate, an anti-EGFR therapy. | | | |
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| | 5mg orally once daily for 21 days of a 28-day cycle. | | | |
| GAVRETO™ (pralsetinib) | Adult patients with metastatic rearranged during transfection (RET) fusion- positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test. Adults and pediatrics ≥ 12 years with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. Adults and pediatrics ≥ 12 years with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). | minimum age = 12 | 4 (100mg) | 120 per 30 days |
| GILOTRIF® (afatinib) | First-line treatment of patients with metastatic non-small cell lung cancer | minimum age = 18 | 1 (40mg) | 30 per 30 days |
| | (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test OR treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy. 40 mg by mouth once daily. | | 1 (30mg) 1 (20mg) | |
| GLEOSTINE® (lomustine) | Brain tumors, primary and metastatic, following appropriate surgical and/or radiotherapeutic procedures. Hodgkin's lymphoma in combination with other chemotherapies, following disease progression with initial chemotherapy. 130 mg/m² (round doses to the nearest 5 mg) orally as a single dose; do not administer lomustine more frequently than once every 6 weeks. | minimum age = 0 | N/A | N/A |



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| HEXALEN® (altretamine) | Ovarian cancer: 260 mg/m²/day by mouth divided four times daily for 14 or 21 days of a 28-day cycle. | minimum age = 18 | N/A | N/A |
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| IBRANCE® (palbociclib) | Adult patients with hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine based therapy; or fulvestrant in patients with disease progression following endocrine therapy. 125 mg by mouth once daily with food (with an aromatase inhibitor or fulvestrant) for 21 days followed by 7 days off. *ANC baseline required prior to starting therapy. | minimum age =18 | 1 (75mg, 100mg, 125mg) | 21 per 30 days |
| ICLUSIG® (ponatinib) | Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors and accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated, and T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL. AP-CML, BP-CML, and Ph+ ALL: 45mg by mouth once daily CP-CML: 45mg by mouth once daily with a reduction to 15mg by mouth once daily upon achievement of ≤1% BCR-ABL1. | minimum age = 18 | 3 (15mg) 1 (45mg) | 30 per 30 days |
| IDHIFA® (enasidenib) | Relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. 100mg by mouth once daily. | minimum age = 18 | 2 (50mg) 1 (100mg) | 30 per 30 days |
| IMBRUVICA® (ibrutinib) | Adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) including 17 p deletion or Waldenström's macroglobulinemia (WM): 420 mg taken orally once daily. Adult and pediatric patients 1 year of age and older with chronic graft versus host | minimum age = 1 | 1 (70mg) 1 (140 mg) 1 (280mg) 1 (420mg) | 30 per 30 days (tablets/capsules) 180 per 30 days (suspension) |



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| | disease (cGVHD) after failure of one or more lines of systemic therapy: Patients 12 years of age and older: 420 mg taken orally once daily. Patients 1 to less than 12 years of age: 240 mg/m² taken orally once daily (up to a dose of 420 mg) | | 6 (70 mg/mL) | |
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| INLYTA® (axitinib) | In combination with avelumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC). In combination with pembrolizumab, for the first-line treatment of patients with advanced RCC. As a single agent, for the treatment of advanced RCC after failure of one prior systemic therapy. 5 mg by mouth twice daily with avelumab 800 mg every 2 weeks. 5 mg by mouth 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 by mouth twice daily. | minimum age = 18 | 4 (1mg) 2 (5mg) | 120 per 30 days |
| INQOVI® (decitabine/cedazuridine) | Myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and highrisk International Prognostic Scoring System groups. 1 tablet by mouth once daily on days 1-5 of each 28 day cycle. | minimum age = 18 | 1 (35mg/100mg) | 5 per 28 days |
| INREBIC® (fedratinib) | Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). 400 mg orally once daily with or without food for patients with a baseline | minimum age = 18 | 4 (100mg) | 120 per 30 days |



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| | platelet count of greater than or equal to $50 \times 10/L$. | | | |
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| IRESSA® (gefitinib) | First-line treatment in patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. 250 mg daily with or without food until disease progression or unacceptable toxicity. | minimum age = 18 | 1 (250mg) | 30 per 30 days |
| IWILFIN™ (effornithine) | To reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Dosage based on body surface area (BSA): >1.5m²: 768 mg orally twice a day 0.75m² to 1.5m²: 576 mg orally twice a day 0.5m² to <0.75m²: 384 mg orally twice a day 0.25m² to <0.5m²: 192 mg orally twice a day | minimum age = 0 | 8 (192mg) | 240 per 30 days |
| JAKAFI® (ruxolitinib) | Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea; Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults; Steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older; Chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic | minimum age = 12 | 2 (5mg, 10mg, 15mg, 20mg, and 25mg) | 60 per 30 days |



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| | therapy in adult and pediatric patients 12 years and older. Polycythemia Vera: Start at 10mg by mouth twice daily Myelofibrosis: 5mg-25mg by mouth twice daily. Based on the platelet count. Greater than 200 X 10°/L: 20 mg given by mouth twice daily; 100 X 10°/L to 200 X 10°/L: 15 mg given by mouth twice daily; 50 X 10°/L to less than 100 X 10°/L: 5 mg given by mouth twice daily. Acute Graft Versus Host Disease: Start at 5mg by mouth twice daily Chronic Graft Versus Host Disease: Start at 10mg by mouth twice daily. | | | |
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| JAYPIRCA™ (pirtobrutinib) | Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. 200mg by mouth once daily. | minimum age =18 | 2 (100mg) 1 (50mg) | 60 per 30 days |
| KISQALI® (ribociclib) | 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; or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men. KISQALI: 600mg by mouth once daily for 21 consecutive days followed by 7 days off. | minimum age =18 | 3 (200mg) | 63 per 28 days |
| KISQALI® FEMARA® CO- PACK (ribociclib and letrozole) | Initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer. | minimum age =18 | 3 (200mg) | 63 per 28 days |



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| | KISQALI: 600mg by mouth once daily for 21 consecutive days followed by 7 days off. FEMARA: 2.5mg once daily throughout the 28 day cycle. | | | |
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| KOSELUGO™ (selumetinib) | Treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). 25 mg/m² by mouth twice daily, reduce the dose to 20 mg/m² by mouth twice daily for moderate hepatic impairment (Child-Pugh B). | minimum age = 2 | 8 (10mg) 4 (25mg) | 240 per 30 days (10mg) 120 per 30 days (25mg) |
| KRAZATI [™] (adagrasib) | Adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy. 600 mg by mouth twice daily. | minimum age =18 | 6 (200mg) | 180 per 30 days |
| LENVIMA® (lenvatinib) | 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 anti-angiogenic therapy. In combination with pembrolizumab, for the first line treatment of patients with advanced RCC. 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 | minimum age =18 | N/A | 30 per 30 days (4mg) 60 per 30 days (8mg) 30 per 30 days (10 mg) 90 per 30 (12mg) 60 per 30 days (14 mg) 90 per 30 days (18mg) 60 per 30 days (20 mg) 90 per 30 days (24 mg) |



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| LORBRENA® (lorlatinib) | systemic therapy and are not candidates for curative surgery or radiation. DTC: 24 mg by mouth once daily RCC: 18 mg by mouth once daily and 5 mg of everolimus once daily; 20 mg orally once daily with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks. HCC: 12 mg by mouth once daily for patients ≥ 60 kg or 8 mg by mouth once daily for patients < 60 kg. Endometrial Carcinoma: 20mg by mouth once daily with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks. Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. | minimum age =18 | 1 (100mg) 3 (25mg) | 30 per 30 days (100mg) 90 per 30 days (25mg) |
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| LONSURF® (trifluridine and tipiracil) | Metastatic colorectal cancer after failure of standard agents (fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy); Metastatic gastric cancer or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy: 35 mg/m² (based on the trifluridine component) by mouth twice daily on days 1-5 and 8-12 of a 28-day cycle (max single dose= | minimum age = 18 | N/A | 80 per 30 days |
| LUMAKRAS® (sotorasib) | KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer | minimum age=18 | 8 (120mg) | 240 per 30 days |



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| | (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. 960mg by mouth once daily. | | 3 (320mg) | |
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| LYNPARZA® (olanarih) | Ovarian cancer: | minimum age=18 | 4 (150mg) | 120 per 30 days |
| LYNPARZA® (olaparib) tablets | a) Maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. b) In combination with bevacizumab for the maintenance treatment of adult patients 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: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. c) Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in | minimum age=18 | 4 (150mg) 4 (100mg) | 120 per 30 days |
| | complete or partial response to platinum-based chemotherapy. | | | |
| | Breast cancer: | | | |
| | Adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, | | | |



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| b) | adjuvant, or metastatic setting. Patients with hormone receptor (HR)- positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. Adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)- positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. | |
|----|--|--|
| Pa | ancreatic cancer: | |
| a) | | |
| Pı | rostate cancer: | |
| a) | Adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA- | |



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| LYSODREN® (mitotane) | approved companion diagnostic for Lynparza. 300mg by mouth twice daily. Adrenocortical carcinoma: 9-10 g/day by mouth divided three times daily to four times daily; max: 19 g/day. | minimum age = 18 | 38 (500mg) | 1,140 per 30 days |
|------------------------|---|------------------|------------|-------------------|
| LYTGOBI® (futibatinib) | Adult patients with previously treated unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. 20 mg orally (five 4 mg tablets) once daily with or without food at approximately the same time each day. | minimum age = 18 | 5 (4mg) | 150 per 30 days |
| MEKTOVI® (binimetinib) | Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test, in combination with encorafenib. 45 mg by mouth twice daily. | minimum age = 18 | 6 (15mg) | 180 per 30 days |
| NERLYNX® (neratinib) | Adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab based therapy; 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, in combination with capecitabine. 240mg by mouth once daily as adjuvant treatment; 240mg by mouth once daily on days 1-21 of a 21-day cycle plus capecitabine Dose escalation: 120mg daily on days 1-7, 160mg daily on days 8-14, then 240mg daily thereafter. | minimum age =18 | 6 (40mg) | 180 per 30 days |
| NEXAVAR® (sorafenib) | Advanced renal cell carcinoma, unresectable hepatocellular carcinoma, locally recurrent or metastatic, progressive, | minimum age =18 | 4 (200mg) | 120 per 30 days |



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| | differentiated thyroid carcinoma refractory to radioactive iodine treatment. 400mg by mouth twice daily without food. | | | |
|-------------------------|--|---------------------------|--|---|
| NILANDRON® (nilutamide) | Metastatic prostate cancer. 300mg once daily for 30 days then 150mg once daily thereafter. | minimum age =18 | 2 (150mg) for one month then 1 (150mg) | 60 per 30 days for one month then 30 per 30 days |
| NINLARO® (ixazomib) | Multiple myeloma in combination with lenalidomide and dexamethasone in patients who have received at least one prior therapy: 4 mg once daily on days 1, 8 and 15 of a 28 day cycle | minimum age = 18 | 1 (4mg) 1 (3mg) 1 (2.3mg) | 3 per 30 days |
| NUBEQA™ (darolutamide) | Patients with non-metastatic castration-resistant prostate cancer (nmCRPC). Patients with metastatic hormone-sensitive prostate cancer (mHSPC), in combination with docetaxel. 600mg by mouth twice daily. | minimum age = 18 | 4 (300mg) | 120 per 30 days |
| ODOMZO® (sonidegib) | Locally advanced basal cell carcinoma if not candidates for surgery or radiation 200 mg by mouth daily. | minimum age = 18 | 1 (200mg) | 30 per 30 days |
| OGSIVEO™ (nirogacestat) | Adult patients with progressing desmoid tumors that require systemic treatment. 150 mg by mouth twice daily. | minimum age = 18 | 6 (50mg) 2 (100mg) 2 (150mg) | 180 per 30 days (50mg) 60 per 30 days (100mg and 150mg) |
| OJEMDA™ (tovorafenib) | For the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. Recommended dosage based on body surface area (BSA) is 380 mg/m² orally once weekly; maximum dosage is 600 mg orally once weekly. | minimum age = 6 months | 6 (100mg) 24 (25mg/mL) | 24 per 28 days (100mg) 96 per 28 (25mg/mL) |



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| OJJAARA™ (momelotinib) | For the treatment of intermediate or highrisk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia 200 mg by mouth once daily. | minimum age = 18 | 1 (100mg) 1 (150mg) 1 (200mg) | 30 per 30 days |
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| ONUREG® (azacitidine) | For continued treatment of adults with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy. 300 mg by mouth once daily on days 1-14 of a 28-day cycle | minimum age = 18 | 1 (200mg) 1 (300mg) | 14 per 28 days |
| ORGOVYX® (relugolix) | Adults with advanced prostate cancer. 360 mg on the first day of treatment followed by 120 mg taken by mouth once daily | minimum age = 18 | 1 (120mg) | 30 per 30 days |
| ORSERDU™ (elacestrant) | For the treatment of postmenopausal women or adult men, with ER positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. | minimum age = 18 | 3 (86 mg) 1 (345mg) | 90 per 30 days (86mg); 30 per 30 days (345mg) |
| | 345 mg taken orally with food once daily at approximately the same time each day. | | | |
| | The recommended dose reduction levels for adverse reactions: 1st dose reduction - 258mg (three 86mg tablets) once daily. 2nd dose reduction - 172mg (two 86mg tablets) once daily. | | | |
| PEMAZYRE™ (pemigatinib) | Adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. 13.5 mg by mouth once daily for 14 consecutive days | minimum age = 18 | 1 (4.5mg) 1 (9mg) 1 (13.5mg) | 30 per 30 days |



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| PIQRAY® (alpelisib) | followed by 7 days off therapy in 21-day cycles. Adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement. 13.5 mg by mouth orally once daily. In combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. 300mg by mouth once daily. | minimum age = 18 | 2 (150mg) 1 (200mg) 1 (50mg) | 60 per 30 days |
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| POMALYST® (pomalidomide) | Adult patients with multiple myeloma (MM) in combination with dexamethasone who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. 4 mg per day taken orally on Days 1 through 21 of repeated 28-day cycles until disease progression. Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative. 5 mg per day taken orally on days 1 through 21 of repeated 28-day cycles until disease progression. | minimum age = 18 | 1 (1mg) 1 (2mg) 1 (3mg) 1 (4mg) | 21 per 30 days |
| PURIXAN® (mercaptopurine oral suspension) **Considered only in patients who cannot swallow tablets** | Acute lymphoblastic leukemia <u>Maintenance</u> : 1.5 to 2.5 mg/kg (50 to 75 mg/m²) by mouth as a single daily dose. | N/A | N/A | **Considered only in patients who cannot swallow tablets** 100 mL/30 days |
| QINLOCK [™] (ripretinib) | Adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with 3 or more kinase inhibitors, including imatinib. | minimum age = 18 | 3 (50mg) | 90 per 30 days |



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| | 150mg by mouth once daily. | | | |
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| RETEVMO™ (selpercatinib) | Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusionAdult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic therapy or who have no satisfactory alternative treatment options. Less than 50 kg: 120 mg by mouth twice daily 50 kg or greater: 160 mg by mouth twice daily | minimum age = 12 | 6 (40mg) 4 (80mg) | 180 per 30 days |
| REZLIDHIA™ (olutasidenib) | Adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. 150mg by mouth twice daily, until disease progression or unacceptable toxicity. | minimum age = 18 | (2) 150mg | 60 per 30 days |
| ROZLYTREK® (entrectinib) | Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive as detected by an FDA-approved test. Adult and pediatric patients 1 month of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion as detected by an FDA-approved test without a known acquired resistance mutation, are metastatic | minimum age = 0 | (12) 50 mg (5) 100mg (3) 200mg | 360 per 30 days |



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| | or where surgical resection is likely to result in severe morbidity and have progressed following treatment or have no satisfactory alternative therapy. For ROSI-Positive Non-Small Cell Lung Cancer: 600mg by mouth once daily. For NTRK Gene Fusion-Positive Solid Tumors: Adults - 600mg by mouth once daily. Pediatric Patients: Based on body surface area (BSA) as shown below: >6 months: BSA ≥ 1.51 m²: 600 mg by mouth once daily; BSA 1.11 to 1.50 m²: 400 mg by mouth once daily; BSA 0.81 to 1.10 m²: 300 mg by mouth once daily; BSA 0.51 to 0.80 m²: 200 mg by mouth once daily; BSA 0.51 to 0.80 m²: 200 mg by mouth once daily; BSA 0.51 to 0.80 m²: 300 mg/ m² >1 month to ≤ 6 months: 250 mg/ m² once daily | | | |
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| RUBRACA® (rucaparib) | Maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic) associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinumbased chemotherapy. Treatment of adult patients 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. 600mg by mouth twice daily. | minimum age = 18 | 4 (300mg) 4 (250mg) 4 (200mg) | 120 per 30 days |
| RYDAPT® (midostaurin) | Newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by a FDA approved test; in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy; the treatment | minimum age = 18 | 8 (25mg) | 224 per 28 days |



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| of patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). AML: 50 mg by mouth twice daily with food on days 8 to 21 of each cycle of induction with cytarabine and daunorubicin and on days 8 to 21 of each cycle of consolidation with high-dose cytarabine. ASM, SM-AHN, and MCL: 100 mg by mouth twice daily. | | | |
| Adults with Philadelphia chromosome- positive (Ph+) chronic myeloid leukemia (CML) in chronic phase who also have the T3151 mutation; Adults with Philadelphia chromosome- positive (Ph+) chronic myeloid leukemia (CML) in chronic phase who previously received two (2) or more tyrosine kinase inhibitors. Ph+ CML in CP: 80 mg orally once daily or 40 mg twice daily. Ph+ CML in CP with the T315I Mutation: 200 mg orally twice daily. | minimum age = 18 | 20mg 40mg | 300 per 30 days |
| Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase; adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib; adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy; pediatric patients 1 year of age and older with Ph+ CML in chronic phase; pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in adults. Chronic phase CML in adults: 100mg by mouth daily | N/A | 2 (20mg, 80mg) 1 (50mg, 70mg, 100mg, 140mg) | 60 per 30 days (20mg, 80mg); 30 per 30 days (50mg, 70mg, 100mg, 140mg) |



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| STIVARGA® (regorafenib) | Accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL in adults: 140mg by mouth daily. Chronic phase CML and ALL in pediatrics dose is based on body weight and should be recalculated at least every 3 months: 10 to < 20kg: 40mg, 20 to < 30kg: 60mg, 30 to <45kg:70mg, 45kg: 100mg Hepatocellular carcinoma who have been previously treated with Sorafenib; Locally advanced, unresectable or metastatic gastrointestinal stromal tumor who have been previously treated with imatinib mesylate and sunitinib malate; | minimum age = 18 | 4 (40mg) | 120 per 30 days |
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| TABRECTA™ (capmatinib) | Metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy: 160 mg by mouth once daily for the first 21 days of each 28-day cycle. Treatment of adult patients with metastatic | minimum age = 18 | 4 (150mg) | 120 per 30 days |
| TABRECTA (capinaunio) | non-small cell lung cancer whose tumors have a mutation that leads to mesenchymalepithelial transition exon 14 skipping as detected by an FDA-approved test. 400 mg by mouth twice daily with or without food. | minimum age = 16 | 4 (200mg) | 120 per 30 days |
| TAGRISSO® (osimertinib) | 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; Adjuvant therapy after tumor resection in adult patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test; Single agent for metastatic EGFR T790M mutation positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy. | minimum age = 18 | 1 (80mg) 1 (40mg) | 30 per 30 days |



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| | 80 mg by mouth once daily. | | | |
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| TALZENNA™ (talazoparib) | For adult patients with deleterious or suspected deleterious germline BRCA-mutated (<i>gBRCAm</i>) HER2-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic test. 1mg by mouth once daily. | minimum age = 18 | 4 (0.25mg) 2 (0.5mg) 1 (0.75mg) 1 (1mg) | 30 per 30 days |
| TARCEVA® (erlotinib) | Metastatic non-small cell lung cancer in patients whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen: 150 mg by mouth daily. First line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine: 100 mg by mouth daily. | minimum age = 18 | 1 (25mg, 100mg, 150mg) | 30 per 30 days |
| TARGRETIN® (bexarotene) | Capsule: Cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy: 300 mg/m²/day. | minimum age = 18 | N/A | N/A |
| TASIGNA® (nilotinib) | Adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase; treatment of adult patients with chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myelogenous leukemia (Ph+CML) resistant or intolerant to prior therapy that included imatinib; treatment of pediatric patients greater than or equal to 1 year of age with chronic phase (CP) or accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) with | minimum age = 1 | 4 (200mg) 4 (150mg) 4 (50mg) | 120 per 30 days |



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| | resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy. Newly diagnosed Ph+ CML-CP: 300 mg orally twice daily for adults. Resistant or intolerant Ph+ CML-CP and CML-AP: 400 mg orally twice daily for adults Pediatric patients: 230mg/m² twice daily | | | |
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| TAZVERIK™ (tazemetostat) | (maximum single dose of 400mg) Treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an enhancer of zeste homolog 2 (EZH2) mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies. Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options. | minimum age = 16 | (8) 200mg | 240 per 30 days |
| TEPMETKO ® (tepotinib) | Adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial transition (MET) exon 14 skipping alterations. (Note: An FDA-approved test for detection of MET exon 14 skipping alterations in NSCLC for selecting patients for treatment with TEPMETKO is not available). 450 mg by mouth once daily. | minimum age = 18 | 2 (225mg) | 60 per 30 days |
| THALOMID® (thalidomide) | Newly diagnosed multiple myeloma (MM) in combination with dexamethasone. Acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). MM: 200mg by mouth once daily with dexamethasone 40mg per | minimum age = 12 | (7) 50mg (3) 100mg (2) 150mg | 210 per 30 days |



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| | day on days 1-4, 9-12 and 17-20 every 28 days. ENL: 100mg to 300mg by mouth daily for an episode of cutaneous ENL. Up to 400mg by mouth per daily for severe cutaneous ENL. | | (2) 200mg | |
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| TIBSOVO® (ivosidenib) | Patients with a susceptible IDH1 mutation as detected by an FDA-approved test with: Relapsed or refractory acute myeloid leukemia (AML) in adults; Patients with newly diagnosed AML who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy; Locally advanced or metastatic cholangiocarcinoma in adults who have been previously treated. 500mg by mouth once daily. | minimum age = 18 | 2 (250mg) | 60 per 30 days |
| TORPENZ™ (everolimus) | 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 renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery; Adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. Breast Cancer: 10 mg orally once daily. TSC-Associated Renal Angiomyolipoma: 10 mg orally once daily. TSC-Associated SEGA: 4.5 mg/m² orally once daily; adjust dose to attain trough concentrations of 5 to 15 ng/mL. | minimum age = 1 | 4 (2.5 mg) 2 (5 mg) 1 (7.5 mg) 1 (10 mg) | 120 per 30 days (2.5 mg) 60 per 30 days (5 mg) 30 per 30 days (7.5mg, 10 mg) |



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| | Note: Torpenz tablets and Afinitor Disperz cannot be combined to achieve the total daily dose of everolimus. | | | |
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| TRUQAP [™] (capivasertib) | In combination with Fulvestrant, for the treatment of adult patients diagnosed with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. 400 mg by mouth twice daily on days 1 through 4, every 7 days | minimum age = 18 | 4 (160mg) 4 (200mg) | 64 per 28 days |
| TRUSELTIQ™ (infigratinib) | Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. 125mg by mouth for 21 days, followed by 7 days off, in a 28-day cycle. Mild and Moderate Renal Impairment/Mild Hepatic Impairment: 100mg by mouth for 21 days, followed by 7 days off, in a 28-day cycle. Moderate Hepatic Impairment: 75mg by mouth for 21 days, followed by 7 days off, in a 28-day cycle | minimum age = 18 | 1 (100mg) 3 (25mg) | 63 per 28 days |
| TUKYSA® (tucatinib) | 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. In combination with trastuzumab for the treatment of adult patient with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has | minimum age = 18 | 4 (50mg) 4 (150mg) | 120 per 30 days |



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| | progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. 300 mg by mouth twice daily with or without food. | | | |
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| TURALIO™ (pexidartinib) | Adult patients with symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery. 250 mg orally twice daily with a low-fat meal (approximately 11 to 14 grams of total fat). | minimum age = 18 | 4 (200mg) 4 (125mg) | 120 per 30 days |
| TYKERB® (lapatinib) | HER2- positive metastatic breast cancer: 1,250-1,500 mg by mouth daily (dose modifications may require dosages as high as 5,500mg/day). | minimum age = 18 | 6 (250mg) | 180 per 30 days |
| VANFLYTA® (quizartinib) | Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. 35.4 mg orally once daily with chemotherapy, 26.5 mg to 53 mg orally once daily as maintenance. | minimum age = 18 | 2 (17.7 mg) 2 (26.5 mg) | 60 per 30 days |
| VENCLEXTA® (venetoclax) | Chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL). In combination with azacitidine or decitabine or low-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. CLL/SLL: ramp up schedule over 5 weeks to the achieved dose of 400mg by | minimum age = 18 | 2 (10mg) 1 (50mg) 6 (100mg) | Starting Pack = 42 per 30 days, $100 \text{ mg} = 180 \text{ per } 30 \text{ days}$ |



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| | mouth once daily. AML: ramp up schedule over 4 weeks to 400mg-600mg by mouth daily. | | | |
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| VEPESID® (etoposide) | Small cell lung cancer: Oral dose is two times the IV dose: (e.g. two times 35 mg/m²/day for 4 days to 50mg/m²/ day for 5 days) rounded to the nearest 50 mg. | N/A | N/A | N/A |
| VITRAKVI® (larotrectinib) | Adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity and have no satisfactory alternative treatments or that have progressed following treatment. Adults and pediatric patients with body surface area of at least 1.0 m²: 100mg by mouth twice daily. Pediatric patients with body surface area of less than 1.0 m²: 100mg/m² by mouth twice daily. | N/A | 6 (25mg) 2 (100mg) 5 (20mg/ml) | 90 per 30 days |
| VIZIMPRO® (dacomitinib) | 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. 45mg by mouth once daily. | minimum age = 18 | 1 (15mg, 30mg, 45mg) | 30 per 30 days |
| VONJO TM (pacritinib) | Intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis in adults with a platelet count below 50×10^9 /L. 200mg by mouth twice daily. | minimum age = 18 | 4 (100mg) | 120 per 30 days |
| WELIREG™ (belzutifan) | Adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery. 120mg by mouth daily. | minimum age = 18 | 3 (40mg) | 90 per 30 days |



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| XALKORI® (crizotinib) | Metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA approved test. 250mg orally twice daily. Unresectable, recurrent, or refractory ALK-positive inflammatory myofibroblastic tumor (IMT) in adult and pediatric patients ≥ 1 year of age. Pediatric: 280 mg/m² orally twice daily; Adult: 250mg orally twice daily. For the treatment of pediatrics ≥ 1 year of age and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. 280 mg/m² orally twice daily. | minimum age = 1 | 2 (200mg, 250mg) | 60 per 30 days |
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| XOSPATA® (gilteritinib) | Relapsed or refractory acute myeloid leukemia with a FMS-like tyrosine kinase 3 mutation as detected by an FDA approved test. 120mg by mouth once daily. | minimum age = 18 | 3 (40mg) | 90 per 30 days |
| XPOVIO™ (selinexor) | Relapsed or refractory multiple myeloma (RRMM) in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. Used in combination with dexamethasone. For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy. In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. RRMM: 80mg by mouth on days 1 and 3 of each week. | minimum age = 18 | 4 (20mg) 40mg, 50mg, 60mg | 32 per 30 days |



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| YONSA®(abiraterone acetate) | DLBCL: 60 mg by mouth on days 1 and 3 of each week. Multiple Myeloma in Combination with bortezomib and dexamethasone: 100 mg taken orally once weekly. Metastatic castration resistant prostate cancer in combination with methylprednisolone. 500 mg by mouth once daily. | minimum age = 18 | 4 (125mg) | 120 per 30 days |
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| ZELBORAF® (vemurafenib) | Metastatic or unresectable melanoma with BRAF V600E mutation; Erdheim-Chester Disease with BRAF V600 mutation as detected by an FDA-approved test: 960mg by mouth every 12 hours. | minimum age = 18 | 8 (240mg) | 240 per 30 days |
| ZEJULA® (niraparib) | 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 patients weighing less than 77 kg (170 lbs) OR with a platelet count of less than 150,000/μL, the recommended dose is 200 mg by mouth once daily. For patients weighing greater than or equal to 77 kg (170 lbs) AND who have a platelet count greater than or equal to 150,000/μL, the recommended dose is 300 mg by mouth once daily. For the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. 300 mg by mouth once daily | minimum age = 18 | 1 (100mg) 1 (200mg) 1 (300mg) | 30 per 30 days |
| ZOLINZA® (vorinostat) | Cutaneous T-cell lymphoma: 400 mg by mouth daily. | minimum age = 18 | 4 (100mg) | 120 per 30 days |



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| ZYDELIG® (idelalisib) | Treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, for whom rituximab alone would be considered appropriate therapy due to other comorbidities. 150mg by mouth twice daily. | minimum age = 18 | 2 (100mg) 2 (150mg) | 60 per 30 days |
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| ZYKADIA®(ceritinib) | Metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase positive as detected by the FDA approved test: 750mg by mouth once daily. | minimum age = 18 | 5 (150mg) | 150 per 30 days |