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Policy Evaluation: Oncology Prior Authorization (PA) Criteria in Oregon Medicaid

Research Questions:

- What are the most common cancer diagnoses in Oregon Medicaid fee-for-service (FFS)?
- What are the most common newer antineoplastic medications prescribed before and after the oncology prior authorization (PA) was implemented in 2020?
- How has the implementation of the 2020 oncology PA criteria impacted the proportion of paid and denied claims?
- What is the proportion of newer oncology agents prescribed for FDA-approved indications or with strong recommendations from the National Comprehensive Cancer Network (NCCN)?
- How have costs for antineoplastic medications changed over time?

Conclusions:

- There has been an increase in utilization and cost of newer antineoplastic agents in the Oregon Medicaid FFS program with most prescribed agents being monoclonal antibodies (43.2%) and kinase inhibitors (24.4%). Despite lower utilization of newer antineoplastic agents compared to older agents, they represent a significant total cost to Oregon Medicaid FFS program which is increasing over time.
- The most common cancer diagnoses for newer antineoplastic medications are leukemia, kidney, lung, and breast cancer.
- Of the 37 members with newer antineoplastic medications in the post-PA group, 14 had an initial denied claim (37.8%). However, 12 of the 14 had a subsequent paid claim within 90 days.
- In the post-PA group, all newer antineoplastics were prescribed for FDA approved indications and NCCN supported indications. Furthermore, 20 patients (54%) were prescribed drugs that were FDA approved through the accelerated approval pathway and 4 included indications that were later withdrawn from the market.

Recommendations:

- Continue with PA for newer antineoplastic medications **(Appendix 1)** due to high costs of medications, ongoing accelerated approvals, and no evidence of a barrier in access or delay in therapy from the PA policy.
- Update prior authorization criteria to include new, recently approved antineoplastic drugs.
- Implement evidence-based step therapy for certain cancer indications supported by clinical guidelines.

Background:

In the US, cancer is the second leading cause of death, with 602,347 cancer related deaths reported in 2020 and 403 new cancer cases reported for every 100,000 people.[1] In 1992, the FDA passed the Accelerated Approval regulation that allowed drugs indicated for serious conditions to be approved based on a

surrogate maker rather than a clinical endpoint.[2] Confirmatory trials demonstrating clinical benefit are required after FDA accelerated approval and indications can be withdrawn if clinical benefit is not proven.[2,3] Currently, the majority of drugs approved through accelerated approval are indicated for cancer.[4] Between 2013 to 2017, 129 cancer drugs were granted approval through the accelerated approval pathway by the FDA.[5] Of the 46 indications with more than 5 years of follow up, 10 indications (22%) were withdrawn from the market after an average of 3.6 years from accelerated approval date to withdrawal date.[5] The increased number of antineoplastic medications approved through the accelerated approval pathway has resulted in reliance on surrogate markers that may not always demonstrate clinical benefit to patients with these unmet benefits.[6]

The NCCN clinical practice guidelines in oncology include recommendations for the prevention, diagnosis, and management of malignancies. The NCCN guidelines are created by multidisciplinary team of specialists to evaluate efficacy and safety in their recommendations, and if high level evidence are not available, clinical experts and researchers are additionally brought in for discussion of guideline recommendations.[7] The NCCN categories for recommendations are included in **Table 1.** NCCN categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel. The NCCN evidence rating is independent of FDA indication, and some diagnoses may have recommended treatment options that are on label or off-label supported by the same NCCN evidence rating.

Table 1: National Comprehensive Cancer Network Categories for Recommendations[7]

Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate
For the 'Uniformed NCCN consensus' defined in Category 1 and 2A, a majority Panel vote of at least 85% is required. For the 'NCCN consensus' defined in Category 2B, a Panel vote of at least 50% (but less than 85%) is required. Strong Panel disagreement regardless of the quality of evidence is a vote of at least 25%.	

To prevent experimental use of these newly approved antineoplastics, Oregon Medicaid implemented a prior authorization (PA) policy in 2020 for these medications (**Appendix 1**). The aim of this PA is to ensure appropriate use of medication that allows for clinical benefit, manage costs to ensure resources are used to benefit the greatest number of patients, and to avoid experimental uses of medications that have limited evidence in therapy. There are currently 230 antineoplastics that fall under this policy. Antineoplastic medications approved prior to 1/1/2008 are exempt from the PA requirements. This policy evaluation aims to assess the impact of the PA criteria implemented for newer oncology medications.

Methods:

Members were identified for inclusion in this study based on a paid or denied FFS pharmacy or medical claim for an antineoplastic drug in First DataBank standard therapeutic class 30 (designating antineoplastic drugs). The evaluation windows for antineoplastic utilization were the 3 years before (10/1/2017 to 09/30/20) and 3 years after (01/21/2021 to 12/30/2023) implementation of PA criteria for newer antineoplastic agents. The index event (IE) was defined as the first paid or denied antineoplastic claim in the evaluation window. Denied claims were included if they had an error code indicating PA was required and did not have any error codes indicating billing errors (see codes in **Appendix 2**). If members had paid and denied claims on the same day, then the IE was classified as paid.

For each patient, the baseline and follow-up periods were based on the IE. The baseline period was defined as the 60 days prior to the IE (exclusive of the IE) and the follow-up period was defined as the 60 days following the IE (inclusive of the IE). Subjects with primary insurance coverage (i.e. third-party liability) at any

time during the baseline or follow-up period were excluded. Additional exclusion criteria included: non-continuous Medicaid eligibility during the baseline period, non-continuous FFS eligibility during the follow-up period, an IE in both evaluation windows, subjects with Medicare part D coverage or limited or no Medicaid drug benefit. Patients were identified based on the following benefit packages:

Category	Benefit Package	Description
Medicare Part D coverage	BMM	Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug
	BMD	Oregon Health Plan with Limited Drug
	MED	Qualified Medicare Beneficiary
Limited or no Medicaid drug benefit	MND	Transplant package
	CWM	Citizenship Waived Emergency Medical
	SMF	Special Low-Income Medicare Beneficiary Only
	SMB	Special Low-Income Medicare Beneficiary Only

Population descriptors and definitions included:

- Demographics at the time of the IE (race, age)
- Claim type (pharmacy, outpatient medical, professional medical)
- People with and without prior claims for the IE drug (based on HICL Sequence Number [HSN]) during the baseline period
- Antineoplastic drugs were categorized based on PDL class (newer vs. older agents), mechanism, and cancer indication (solid tumor, blood cancer, or both)
- Provider type based on primary taxonomy (**Appendix 2**) of the prescribing provider for pharmacy claims. For medical claims, the provider was classified as a hematologist/oncologist if any of the provider fields (billing, attending, or performing providers) on the claim were associated with the taxonomies in **Appendix 2**.

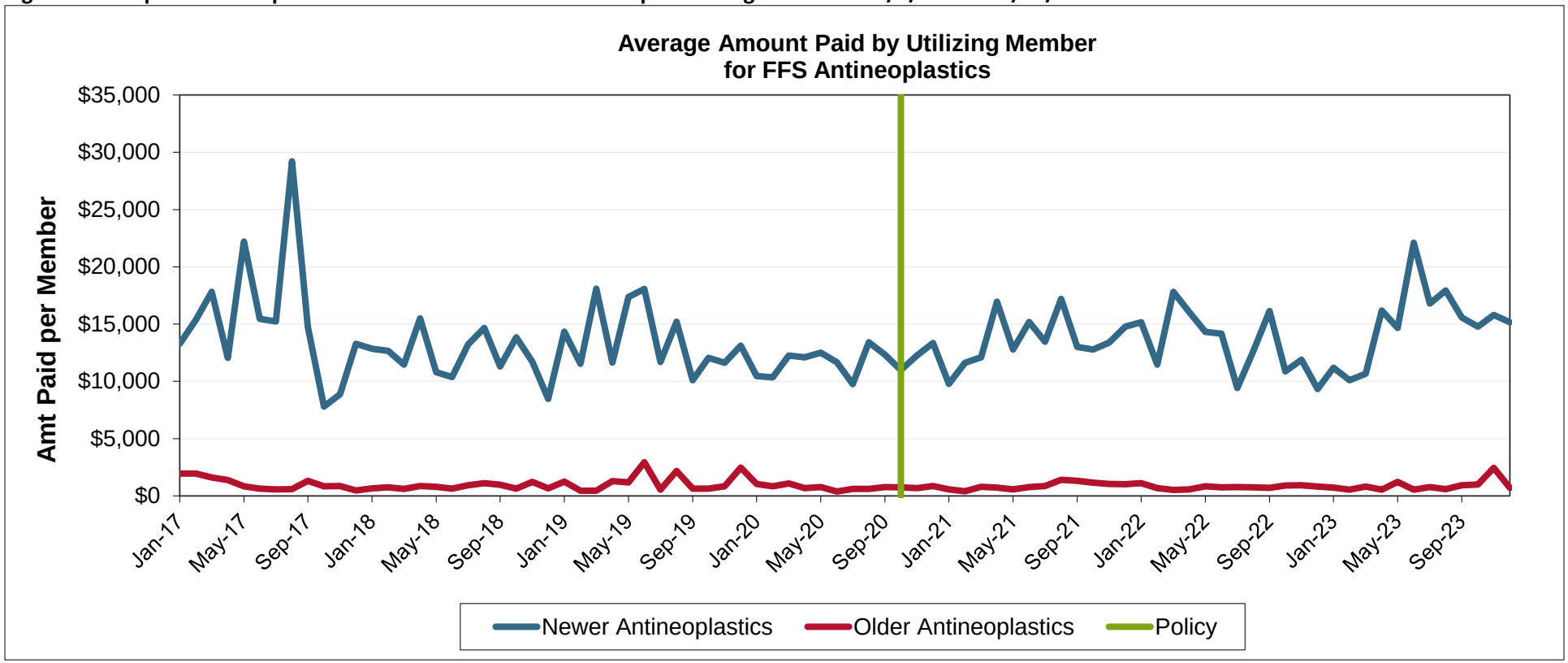
Outcomes that were planned for this analysis included:

- Type of cancer diagnosis. For pharmacy claims, diagnoses were identified based on medical claims the 6 months prior to the IE. For medical claims, diagnoses were identified based on the diagnosis submitted on the IE. Diagnoses for any of the most common cancer types diagnosed with the greatest frequency in the United States according to the National Cancer Institute were included.[8]
- Proportion of people with paid or denied claims for newer antineoplastic drugs
- Proportion of people with denied claims after PA criteria implementation who had a subsequent PA submission and approval

Results:

In January 2020, the Oregon Medicaid Fee-for-Service (FFS) program implemented a prior authorization (PA) policy for antineoplastic agents approved by the Food and Drug Administration (FDA) after 2008. Agents approved prior to 2008 are defined as older antineoplastics. **Figure 1** illustrates the cost per member per month for both newer and older antineoplastic agents from 2017 to 2023.

Figure 1. Cost per member per month for older and new antineoplastic drugs between 10/1/2017 to 9/30/2023



The overall amount paid per member remained relatively consistent for newer and older antineoplastic agents following the PA implementation compared to the pre-implementation period with a higher cost per member for newer antineoplastics compared to older antineoplastics.

Despite the consistent per-member spending, **Table 1** demonstrates that the total drug costs and for newer antineoplastics have increased annually since 2017, accompanied by increased utilizing members and claim count. Conversely, total drug cost and claim count of older antineoplastics has decreased from 2017 to 2023. Table 1 excludes those with limited benefit, Medicare, and third-party liability (TPL).

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Table 1: Annual total: FFS paid pharmacy and medical claims for older and newer antineoplastics

Year	Total drug cost	Utilizing Members	Cost per member	Claim count	Cost per claim
Newer Antineoplastics					
2017	$1,926,772	58	$33,220	232	$8,305
2018	$1,190,789	51	$23,349	145	$8,212
2019	$2,306,857	65	$35,490	324	$7,120
2020	$2,641,200	81	$32,607	348	$7,590
2021	$2,686,936	60	$44,782	402	$6,684
2022	$3,126,184	81	$38,595	534	$5,854
2023	$3,920,265	89	$44,048	447	$8,770
Older Antineoplastics					
2017	$1,870,660	671	$2,788	3,215	$582
2018	$1,041,488	559	$1,863	2,257	$461
2019	$1,383,199	459	$3,014	3,116	$444
2020	$858,538	406	$2,115	2,070	$415
2021	$873,519	339	$2,577	1,832	$477
2022	$710,579	336	$2,115	1,849	$384
2023	$774,140	301	$2,572	1,603	$483

After exclusion criteria, there were a total of 27 subjects with a claim for a newer antineoplastic prior to the PA implementation and 37 after PA implementation (**Table 2**). The number of FFS members with a claim for an older antineoplastic decreased from 358 prior to PA to 274 after PA implementation.

Table 2. Number of people included in the analysis based on each exclusion criteria

	Pre-Implementation		**Post Implementation**	
	Older	**Newer**	**Older**	**Newer**
Members with a FFS paid or denied pharmacy or medical claim	2,245	392	1,726	507
After exclusion of Medicare and TPL	1,056 (47.0 %)	90 (23.0 %)	639 (37.0 %)	114 (22.5 %)
After exclusion for continuous Medicaid enrollment in the baseline period	903 (40.2 %)	84 (21.4 %)	569 (33.0 %)	93 (18.3 %)
After exclusion for continuous FFS enrollment for the follow-up period	358 (15.9 %)	27 (6.9 %)	342 (19.8 %)	51 (10.1 %)
After exclusion of people with and IE in both groups	358 (15.9 %)	27 (6.9 %)	273 (15.8 %)	37 (7.3 %)
- **Prior treatment** - **No prior treatment**	77 (3.4 %) 281 (12.5 %)	3 (0.8 %) 24 (6.1 %)	21 (1.2 %) 252 (14.6 %)	0 (0.0 %) 37 (7.3 %)

Table 3 presents the demographic characteristics of Medicaid FFS members utilizing antineoplastic agents in Oregon, comparing pre- and post-implementation periods of a PA policy. The average age of members receiving newer antineoplastic agents was similar across both periods, with a mean age of 49 years in the pre-implementation group and 51 years in the post-implementation group. Importantly, new start of newer antineoplastics with no prior treatment comprised 88.9% of requests in the pre-implementation group, increasing to 100% of requests in the post-implementation group. Less than half of newer antineoplastics were pharmacy claims (44.4% pre-PA and 48.6% post-PA) while the remaining were medical claims. Newer antineoplastics were prescribed by an oncology or hematology provider more frequently than the older antineoplastics (63% vs. 37% pre-PA and 48.6% vs. 23.8% post-PA, respectively).

Table 3. Baseline demographics

	Pre implementation				Post implementation			
	Newer Agents		Older Agents		Newer Agents		Older agents	
	n= 27		n=358		n=37		n=273	
Average Age (min-max)	49 (6-63)		45 (3-67)		51 (11-64)		43 (1-76)	
0-18	4	14.8 %	24	6.7 %	1	2.7 %	16	5.9 %
19-64	23	85.2 %	332	92.7 %	36	97.3 %	252	92.3 %
65 +	0	0.0 %	2	0.6 %	0	0.0 %	5	1.8 %
Gender								
Male	13	48.1 %	100	27.9 %	19	51.4 %	64	23.4 %
Female	14	51.9 %	258	72.1 %	18	48.6 %	209	76.6 %
Prior Therapy	3	11.1 %	77	21.5 %	0	0.0 %	21	7.7 %
New Therapy	24	88.9 %	281	78.5 %	37	100.0 %	252	92.3 %
Providing Prescriber								
Oncologist	17	63.0 %	123	34.4 %	18	48.6 %	65	23.8 %
Other	10	37.0 %	235	65.6 %	19	51.4 %	208	76.2 %
Claim Type								
Pharmacy	12	44.4 %	239	66.8 %	18	48.6 %	168	61.5 %
Outpatient medical	7	25.9 %	86	24.0 %	12	32.4 %	71	26.0 %
Professional medical	8	29.6 %	33	9.2 %	7	18.9 %	34	12.5 %

Table 4 presents the distribution of common cancer diagnosis among members utilizing antineoplastic agents, categorized by classification of agents used. Leukemia was the most prevalent diagnosis among members utilizing newer agents in the pre-implementation period. In contrast, breast and prostate cancer were the most common diagnosis associated with newer agent utilization in the post-implementation period. Notably, breast cancer remained the most prevalent diagnosis among members utilizing older antineoplastic agents in both pre- and post- implementation periods.

Table 4. Common cancer diagnoses

	Pre-Implementation						Post Implementation					
	All Agents		Newer Agents		Older Agents		All Agents		Newer Agents		Older Agents	
Indication	**385**	**%**	**27**	**%**	**358**	**%**	**310**	**%**	**37**	**%**	**273**	**%**
Bladder	3	0.8%			3	0.8%	4	1.3%			4	1.5%
Breast	44	11.4%	1	3.7%	43	12.0%	38	12.3%	5	13.5%	33	12.1%
Colon and Rectal	7	1.8%			7	2.0%	9	2.9%	1	2.7%	8	2.9%
Endometrial	1	0.3%			1	0.3%						
Kidney	5	1.3%	3	11.1%	2	0.6%	2	0.6%	2	5.4%		
Leukemia	13	3.4%	4	14.8%	9	2.5%	5	1.6%	3	8.1%	2	0.7%
Liver	7	1.8%	2	7.4%	5	1.4%	2	0.6%	1	2.7%	1	0.4%
Lung	2	0.5%	1	3.7%	1	0.3%	7	2.3%	6	16.2%	1	0.4%
Non-Hodgkin Lymphoma	5	1.3%	2	7.4%	3	0.8%						
Melanoma	1	0.3%	1	3.7%			1	0.3%	1	2.7%		
Pancreatic	2	0.5%			2	0.6%						
Prostate	3	0.8%	1	3.7%	2	0.6%	5	1.6%	5	13.5%		
Thyroid												
Other	64	16.6%	10	37.0%	54	15.1%	58	18.4%	14	37.8%	43	15.8%

Most newer antineoplastics utilized by FFS members were indicated for solid organ tumors (**Table 5**). The most frequently prescribed older antineoplastics were antimetabolites and aromatase inhibitors. The most prescribed newer antineoplastics in both the pre-PA and post-PA groups were monoclonal antibodies (59.4%) and kinase inhibitors (21.9%) (**Table 5**). The overall prescribing patterns of antineoplastic agents did not exhibit a large variation due to the policy change. Consistent with goals of the PA policy, all newer antineoplastic agents were prescribed for FDA approved and NCCN supported indications. Of the 37 newer antineoplastics prescribed in the post-PA group, 20 (54%) were FDA approved through the accelerated approval pathway and 4 included indications that were later removed from the market.

Table 5. Newer antineoplastic agents by drug class

	Pre-PA Implementation	Post-PA Implementation
Drug Class	**Newer Agents (%)**	**Newer Agents (%)**
	27	**37**
Drugs for solid organ tumors		
Antiandrogen	1 (3.7%)	5 (13.5%)
Hedgehog pathway inhibitor		1 (2.7%)
Kinase inhibitor	5 (18.5%)	9 (24.3%)
Monoclonal antibody	12 (44.4%)	16 (43.2%)
Proteasome Inhibitor	1 (3.7%)	1 (2.7%)
Drugs for blood cancer		
Enzyme		1 (2.7%)
Kinase inhibitor	2 (7.4%)	
Miscellaneous		
Monoclonal antibody	6 (22.2%)	4 (10.8%)

Table 6 includes the proportion of people with paid or denied claims for older and newer antineoplastic drugs. All members with prior treatment of newer antineoplastic agents had a PA approved in the post-implementation group. Following the PA implementation in 2020, the proportion of new start treatments with paid index events decreased for 99.7% to 88.9%. For newer antineoplastic drugs only, 14 (37.8%) members had an initial denied claim. However, of the 14 denied claims, 12 had a subsequent paid newer antineoplastic claim within 90 days. Most of these subsequent paid claims were for the same antineoplastic as the original index claim and occurred within the same month.

Table 6. Proportion of people with paid or denied claims for older and newer antineoplastic drugs

Indication	**Pre-PA (Older and Newer)**		**Post-PA (Older and Newer)**		**Post-PA (Newer Only)**
	New Start (%)	Prior Treatment (%)	New Start (%)	Prior Treatment (%)	N (%)
	305	80	289	21	37
People with paid IE	304 (99.7)	80 (100)	257 (88.9)	21 (100)	23 (62.6)
People with denied IE	1 (0.3)	0 (0)	32 (11.1)	0 (0)	14 (37.8)
People with no subsequent paid claim for an antineoplastic drug within 90 days	1 (0.3)	0 (0)	19 (6.6)	0 (0)	2 (5.4)
People with a subsequent paid antineoplastic claim within 90 days	0 (0)	0 (0)	13 (4.5)	0 (0)	12 (32.4)
Subsequent Newer antineoplastic	0 (0)	0 (0)	12 (92.3)	0 (0)	12 (100)
Subsequent older antineoplastic	0 (0)	0 (0)	2 (15.4)	0 (0)	0

Discussion:
Following the application of exclusion criteria, the study cohort comprised 27 patients receiving newer antineoplastic agents in the pre-policy group and 37 patients in the post-policy group. Most prescribing continued to be for older antineoplastic agents in both groups (pre-policy: 93%, post-policy: 88%). Despite this, newer antineoplastic agents represent a significant higher total cost for FFS Medicaid and is increasing every year. Kinase inhibitors (24.4%) and monoclonal antibodies (43.2%) were the most common drug classes of newer antineoplastic agents prescribed which is consistent with the trend in FDA approvals.

Of the 37 patients in the post-policy group prescribed a newer antineoplastic medication, 14 (37.8%) had an initial denied claim. Due to a concern for delayed treatments for members with cancer diagnoses, chart review was done to further evaluate the pattern of denied claims. Of the 14 members with a denied claim in the post-PA group, 12 (86%) had a subsequent paid antineoplastic claim within 90 days, and most of them had a claim within the same month and for the same medication as the index event. One member without a paid claim within 90 days did have a paid claim after 100 days of the initial index event. All newer antineoplastic agents in the post-PA group were prescribed for FDA-approved and NCCN-supported indications. Notably, 20 (54%) of the 37 newer antineoplastic agents in the post-policy group were approved through the FDA's accelerated approval pathway, and four included indications that were later withdrawn from the market.

The implementation of the prior authorization criteria in the OHP FFS pharmacy benefit resulted in very few delays in therapy. The data demonstrates an increase in utilization and cost of newer antineoplastic agents within the FFS program, particularly for monoclonal antibodies and kinase inhibitors which are the most frequently prescribed type of drug. There is an opportunity for future investigation of evidence-based step therapy protocols supported by current clinical guidelines.

Limitations:

- The sample size was relatively small. Only 37 members or 7.3% of the total number of members requesting for newer agents post implementation met criteria for the analysis after applying exclusion criteria. This limited sample size may have reduced the generalizability of the analysis.
- There was a significant amount of missing data within the internal PA text, particularly regarding diagnoses. This limitation prevented the accurate determination of primary oncology diagnoses and the identification of prior use of other antineoplastic agents before secondary diagnoses.
- While all requested agents were initially FDA-approved and supported by NCCN guidelines, some indications for these agents were subsequently withdrawn from the market. To mitigate the risk of utilizing agents with potentially withdrawn indications, the implementation of evidence-based step therapy protocols could be considered as a strategy to optimize medication selection and ensure the most appropriate and up-to-date treatment options for patients.

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Appendix 1: Prior Authorization Criteria

Oncology Agents

Goal(s):

- To ensure appropriate use for oncology medications based on FDA-approved and compendia-recommended (i.e., National Comprehensive Cancer Network® [NCCN]) indications.

Length of Authorization:

- Up to 1 year

Requires PA:

- Initiation of therapy for drugs listed in **Table 1** (applies to both pharmacy and provider administered claims). This does not apply to oncologic emergencies administered in an emergency department or during inpatient admission to a hospital.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1: National Comprehensive Cancer Network (NCCN) Categories for Recommendations

Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate
For the 'Uniformed NCCN consensus' defined in Category 1 and 2A, a majority Panel vote of at least 85% is required. For the 'NCCN consensus' defined in Category 2B, a Panel vote of at least 50% (but less than 85%) is required. Strong Panel disagreement regardless of the quality of evidence is a vote of at least 25%.	

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of an oncologic emergency (e.g., superior vena cava syndrome [ICD-10 I87.1] or spinal cord	**Yes:** Approve for length of therapy (if specified) or 12	**No:** Go to #3

compression [ICD-10 G95.20]) administered in the emergency department?	months, (if duration is unspecified).	
3. Is the request for any continuation of therapy?	**Yes:** Approve for length of therapy (if specified) or 12 months (if duration is unspecified).	**No**: Go to #4
4. Is the diagnosis funded by OHP?	**Yes:** Go to #6	**No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP If eligible for EPSDT review: Go to #5.
5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical necessity.
6. Is the indication FDA-approved for the requested drug? Note: This includes all information required in the FDA-approved indication, including but not limited to the following as applicable: diagnosis, stage of cancer, biomarkers, place in therapy, and use as monotherapy or combination therapy.	**Yes**: Go to #8	**No:** Go to #7
7. Is the indication recommended by National Comprehensive Cancer Network (NCCN) Guidelines® for the requested drug? Note: This includes all information required in the NCCN recommendation, including but not limited to the following as applicable: diagnosis, stage of cancer, biomarkers, place in therapy, and use as monotherapy or combination therapy.	**Yes:** Go to #8	**No:** Go to #9

8. Are there equally or higher recommended alternative agents based on NCCN categories of evidence (Table 1) for the requested indication and place in therapy?	**Yes:** Pass to RPh. Approve for length of therapy (if specified) or 12 months (if duration is unspecified) Note: When efficacy is similar, the choice of agent should be determined by safety, and then cost. In the absence of a safety concern, the prescriber is expected to use the least costly alternative.	**No:** Pass to RPh. Approve for length of therapy (if specified) or 12 months (if duration is unspecified).
9. Is there documentation based on chart notes that the patient is enrolled in a clinical trial to evaluate efficacy or safety of the requested drug?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: The Oregon Health Authority is statutorily unable to cover experimental or investigational therapies.	**No:** Go to #10
10. Is the request for a rare cancer which is not addressed by National Comprehensive Cancer Network (NCCN) Guidelines® and which has no FDA approved treatment options?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness.

11. All other diagnoses must be evaluated for evidence of clinical benefit.

    The prescriber must provide the following documentation:
    - Ÿ medical literature or guidelines supporting use for the condition,
    - Ÿ clinical chart notes documenting medical necessity, and
    - Ÿ documented discussion with the patient about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy.

RPh may use clinical judgement to approve drug for length of treatment or deny request based on documentation provided by prescriber. If new evidence is provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria.

Table 1. Oncology agents which apply to this policy (Updated 3/4/2025)

New Antineoplastics are immediately subject to the policy and will be added to this table at the next P&T Meeting

Generic Name	Brand Name
abemaciclib	VERZENIO
abiraterone acet,submicronized	YONSA
abiraterone acetate	ZYTIGA
abiraterone acetate/niraparib tosylate	AKEEGA
acalabrutinib	CALQUENCE
adagrasib	KRAZATI
ado-trastuzumab emtansine	KADCYLA
afatinib dimaleate	GILOTRIF
afamitresgene autoleucel	TECELRA
alectinib HCl	ALECENSA
amivantamab-vmjw	RYBREVANT
alpelisib	PIQRAY
asciminib	SCEMBLIX
apalutamide	ERLEADA
asparaginase (Erwinia chrysanthemi)	ERWINAZE
asparaginase Erwinia crysanthemi (recombinant)-rywn	RYLAZE
atezolizumab	TECENTRIQ
avapritinib	AYVAKIT
avelumab	BAVENCIO
axicabtagene ciloleucel	YESCARTA
axitinib	INLYTA
azacitidine	ONUREG
belantamab mafodotin-blmf	BLENREP
belinostat	BELEODAQ
belzutifan	WELIREG
bendamustine HCl	BENDAMUSTINE HCL
bendamustine HCl	TREANDA
bendamustine HCl	BENDEKA
binimetinib	MEKTOVI
blinatumomab	BLINCYTO
bosutinib	BOSULIF
brentuximab vedotin	ADCETRIS
brexucabtagene autoleucel	TECARTUS
brigatinib	ALUNBRIG
cabazitaxel	JEVTANA
cabozantinib s-malate	CABOMETYX
cabozantinib s-malate	COMETRIQ
calaspargase pegol-mknl	ASPARLAS
capivasertib	TRUQAP
capmatinib	TABRECTA
carfilzomib	KYPROLIS
cemiplimab-rwlc	LIBTAYO
ceritinib	ZYKADIA
ciltacabtagene autoleucel	CARVYKTI
cobimetinib fumarate	COTELLIC
copanlisib di-HCl	ALIQOPA
cosibelimab-ipdl	UNLOXCYT
crizotinib	XALKORI

Generic Name	Brand Name
dabrafenib mesylate	TAFINLAR
dacomitinib	VIZIMPRO
daratumumab	DARZALEX
daratumumab/hyaluronidase-fihj	DARZALEX FASPRO
darolutamide	NUBEQA
decitabine and cedazuridine	INQOVI
degarelix acetate	FIRMAGON
denileukin diftitox-cxdl	LYMPHIR
dostarlimab-gxly	JEMPERLI
dinutuximab	UNITUXIN
durvalumab	IMFINZI
duvelisib	COPIKTRA
eflornithine	IWILFIN
elacestrant	ORSERDU
elotuzumab	EMPLICITI
elranatamab-bcmm	ELREXFIO
enasidenib mesylate	IDHIFA
encorafenib	BRAFTOVI
enfortumab vedotin-ejfv	PADCEV
ensartinib	ENSACOVE
entrectinib	ROZLYTREK
enzalutamide	XTANDI
epcoritamab-bysp	EPKINLY
erdafitinib	BALVERSA
eribulin mesylate	HALAVEN
everolimus	AFINITOR
everolimus	AFINITOR DISPERZ
fam-trastuzumab deruxtecan-nxki	ENHERTU
fedratinib	INREBIC
fruquintinib	FRUZAQLA
futibatinib	LYTGOBI
gilteritinib	XOSPATA

Generic Name	Brand Name
glasdegib	DAURISMO
glofitamab-gxbm	COLUMVI
ibrutinib	IMBRUVICA
idecabtagene vicleucel	ABECMA
idelalisib	ZYDELIG
imetelstat	RYTELO
infigratinib	TRUSELTIQ
ingenol mebutate	PICATO
inotuzumab ozogamicin	BESPONSA
ipilimumab	YERVOY
isatuximab	SARCLISA
ivosidenib	TIBSOVO
ixazomib citrate	NINLARO
larotrectinib	VITRAKVI
lazertinib	LAZCLUZE
lenvatinib mesylate	LENVIMA
lifileucel	AMTAGVI
lisocabtagene maraleucel	BREYANZI
loncastuximab tesirine-lpyl	ZYNLONTA
lorlatinib	LORBRENA
lurbinectedin	ZEPZELCA
lutetium Lu 177 dotate	LUTATHERA
lutetium Lu 177 vipivotide tetraxetan	PLUVICTO
margetuximab-cmkb	MARGENZA
melphalan flufenamide	PEPAXTO
melphalan hcl/hepatic delivery kit (HDS)	HEPZATO KIT
midostaurin	RYDAPT
mirvetuximab soravtansine-gynx	ELAHERE
mobecertinib	EXKIVITY
momelotinib	OJJAARA
mosunetuzumab-axgb	LUNSUMIO
motixafortide	APHEXDA

Generic Name	Brand Name
moxetumomab pasudotox-tdfk	LUMOXITI
nadofaragene firadenovec-vncg	ADSTILADRIN
naxitamab-gqgk	DANYELZA
necitumumab	PORTRAZZA
neratinib maleate	NERLYNX
niraparib and abiraterone acetate	AKEEGA
niraparib tosylate	ZEJULA
nirogacestat hydrobromide	OGSIVEO
nivolumab	OPDIVO
nivolumab and hyaluronidase-nvhy	OPDIVO QVANTIG
nivolumab; relatlimab-rmbw	OPDUALAG
nogapendekin alfa inbakicept-pmln	ANKTIVA
obecabtagene autoleucel	AUCATZYL
obinutuzumab	GAZYVA
ofatumumab	ARZERRA
olaparib	LYNPARZA
olaratumab	LARTRUVO
olatuzumab vedotin-piiq	POLIVY
omacetaxine mepesuccinate	SYNRIBO
omidubicel-onlv	OMISIRGE
osimertinib mesylate	TAGRISSO
olutasidenib	REZLIDHIA
pacritinib	VONJO
palbociclib	IBRANCE
panobinostat lactate	FARYDAK
pazopanib HCl	VOTRIENT
pembrolizumab	KEYTRUDA
pemigatinib	PEMAZYRE
pertuzumab	PERJETA
pertuzumab/trastuzumab/haluronidase-zzxf	PHESGO
pexidartinib	TURALIO
pirtobrutinib	JAYPIRCA

Generic Name	Brand Name
polatuzumab vedotin-piiq	POLIVY
pomalidomide	POMALYST
ponatinib	ICLUSIG
pralatrexate	FOLOTYN
pralsetinib	GAVRETO
quizartinib	VANFLYTA
ramucirumab	CYRAMZA
regorafenib	STIVARGA
relugolix	ORGOVYX
repotrectinib	AUGTYRO
retifanlimab-dlwr	ZYNYZ
revumenib	REVUFORJ
ribociclib succinate	KISQALI
ribociclib succinate/letrozole	KISQALI FEMARA CO-PACK
ripretinib	QINLOCK
romidepsin	ISTODAX
romidepsin	ROMIDEPSIN
ropeginterferon alfa-2b-njft	BESREMI
rucaparib camsylate	RUBRACA
ruxolitinib phosphate	JAKAFI
sacitizumab govitecan-hziy	TRODELVY
selinexor	XPOVIO
selpercatinib	RETEVMO
siltuximab	SYLVANT
sipuleucel-T/lactated ringers	PROVENGE
sirolimus albumin-bound nanoparticles	FYARRO
sonidegib phosphate	ODOMZO
sotorasib	LUMAKRAS
tafasitamab-cxix	MONJUVI
tagraxofusp-erzs	ELZONRIS
talazoparib	TALZENNA
talimogene laherparepvec	IMLYGIC

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April 2025

Generic Name	Brand Name
talquetamab-tgvs	TALVEY
tarlatamab-dlle	IMDELLTRA
tazemetostat	TAZVERIK
tebentafusp-tebn	KIMMTRAK
teclistamab-cqyv	TECVAYLI
tepotinib	TEPMETKO
tisagenlecleucel	KYMRIAH
tislelizumab-jsgr	TEVIMBRA
tisotumab vedotin-tftv	TIVDAK
tivozanib	FOTIVDA
toripalimab-tpzi	LOQTORZI
tovorafenib	OJEMDA
trabectedin	YONDELIS
trametinib dimethyl sulfoxide	MEKINIST
trastuzumab-anns	KANJINTI
trastuzumab-dkst	OGIVRI
trastuzumab-dttb	ONTRUZANT
trastuzumab-hyaluronidase-oysk	HERCEPTIN HYLECTA
trastuzumab-pkrb	HERZUMA
trastuzumab-qyyp	TRAZIMERA
trastuzumab-strf	HERCESSI
tremlimumab	IMJUDO
trifluridine/tipiracil HCl	LONSURF
trilaciclib	COSELA
tucatinib	TUKYSA
umbralisib	UKONIQ
vandetanib	VANDETANIB
vandetanib	CAPRELSA
vemurafenib	ZELBORAF
venetoclax	VENCLEXTA
venetoclax	VENCLEXTA STARTING PACK
vimseltinib	ROMVIMZA
vismodegib	ERIVEDGE
vorasidenib	VORANIGO
zanidatamab-hrii	ZIIHERA
zanubrutinib	BRUKINSA
zenocutuzumab-Zbco	BIZENGRI
ziv-aflibercept	ZALTRAP

P&T/DUR Review: 6/2020 (JP)
Implementation: 10/1/20

Appendix 2: Drug Codes

Table A1. Error Codes Associated with Denied Claims

Error Code	Description	
3002	NDC REQUIRES PA	Include
4178	Pharmacy Policy Edit - Oncology PAD Requires PA	Include
4173	Pharmacy Policy Edit - PAD Claim Requires PA	Include
3000	UNITS EXCEED AUTHORIZED UNITS ON PA MASTER FILE	Include
3003	PA IS REQUIRED	Include
3001	SERVICES REQUIRE A PA	Include
3101	TIME LIMIT EXCEEDED ON PA	Include
2017	RECIPIENT SERVICES COVERED BY HMO PLAN	Exclude
2508	RECIPIENT COVERED BY PRIVATE INSURANCE (PHARMACY)	Exclude
4999	THIS DRUG IS COVERED BY MEDICARE PART D	Exclude
2017	RECIPIENT SERVICES COVERED BY HMO PLAN	Exclude
5001	EXACT DUPLICATE	Exclude
2504	RECIPIENT COVERD BY PRIVATE INSURANC(NO ATTACHMNT)	Exclude
2509	RECIPIENT COVERED BY MEDICARE	Exclude
5001	EXACT DUPLICATE	Exclude
5000	POSSIBLE DUPLICATE	Exclude
628	Other Coverage Reject Code Required for OCC 3	Exclude
3100	MISMATCH WITH PA PROCEDURE/DIAGNOSIS	Exclude
2505	RECIPIENT COVERED BY PRIVATE INSURANC(W/ATTACHMNT)	Exclude
5000	POSSIBLE DUPLICATE	Exclude
4003	HCPCS PROCEDURE REQUIRES AN NDC	Exclude
2502	RECIPIENT COVERED BY MEDICARE B (NO ATTACHMENT)	Exclude
2507	RECIPIENT HAS MORE THAN ONE INSURANCE CARRIER	Exclude
2503	RECIPIENT COVERED BY MEDICARE B (WITH ATTACHMENT)	Exclude
3322	Quantity disagrees with days billed	Exclude
2507	RECIPIENT HAS MORE THAN ONE INSURANCE CARRIER	Exclude
4004	NDC NOT ON FILE	Exclude
4014	NO PRICING SEGMENT ON FILE	Exclude
3542	DIAGNOSIS REIMBURSABLE W/DIAGNOSTIC PROCEDURES ONL	Exclude
4024	INVALID HCPCS/NDC COMBINATION	Exclude
5005	MCO Billing Provider - Exact Duplicate - Detail	Exclude
2003	RECIPIENT INELIGIBLE ON DETAIL DATE OF SERVICE	Exclude

5005	MCO Billing Provider - Exact Duplicate - Detail	Exclude
5020	NDC Quantity must be greater than zero.	Exclude

Table A2. Taxonomy codes indicating hematology/oncology providers

Taxonomy	Description
163WP0218X	REGISTERED NURSE - PEDIATRIC ONCOLOGY
163WX0200X	REGISTERED NURSE - UNCATEGORIZED: ONCOLOGY
1835X0200X	PHARMACIST - ONCOLOGY
207RH0000X	PHYSICIAN-INTERNAL MEDICINE-HEMATOLOGY
207RH0003X	PHYSICIAN-INTERNAL MEDICINE-HEMATOLOGY&ONCOLOGY
207RX0202X	PHYSICIAN-INTERNAL MEDICINE-MEDICAL ONCOLOGY
207VX0201X	PHYSICIAN-OBSTETRICS & GYNECOLOGY-GYNECOLOGIC ONCOLOGY
207ZH0000X	PHYSICIAN-PATHOLOGY-HEMATOLOGY
2080P0207X	PHYSICIAN-PEDIATRICS-PEDIATRIC HEMATOLOGY ONCOLOGY
2085R0001X	PHYSICIAN-RADIOLOGY-RADIATION ONCOLOGY
2086X0206X	PHYSICIAN-SURGERY-SURGICAL ONCOLOGY
261QX0200X	CLINIC/CENTER - ONCOLOGY
261QX0203X	CLINIC/CENTER - ONCOLOGY
364SX0200X	CLINICAL NURSE SPECIALIST - UNCATEGORIZED: ONCOLOGY
364SX0204X	CLINICAL NURSE SPECIALIST - ONCOLOGY

Appendix 3: ICD Codes

Indication	ICD Codes
Bladder	**C67:** C67.0 - C67.9
Breast (female and male)	**C50:** C50.0 - 50.9
Colon and rectal	**C18:** C18.0 - C18.9 **C17:** C17.1- 17.3, 17.8, 17.9 **C20.0** **C21:** C21.0 - C21.2, C21.8
Endometrial	**C54.1**
Kidney (renal cell and renal pelvis)	**C64:** C65.1, C65.2, C65.9 **C65:** C65.1, C65.2, C65.9
Leukemia	**C91:** C91.0, C91.1, C91.3-C91.6, C91.9, C91.A, C91.Z **C92:**C92.0-C92.6, C92.A, C92.Z, C92.9 **C93:** C93.0, C93.1, C93.3, C93.Z, C03.9 **C94:** C94.0, C94.2, C94.3, C94.4, C94.6, C94.8 **C95:** C95.0, C95.1, C95.9
Liver and intrahepatic bile duct	**C22:** C22.0-C22.4, C22.7-C22.9
Lung	**C34:** C34.0-C34.9
Melanoma	C43
Non Hodgkin lymphoma	**C85:** C85.0-C85.2, C85.8-C85.9
Pancreatic	**C25:** C25.0-C25.4, C25.7-C25.9
Prostate	**C61**
Thyroid	**C73**
Other	Any codes **C00-D49** except for codes listed above

New Antineoplastic Agents					
Drug Class	Drug	Blood, solid, or both	Drug Class	Drug	Blood, solid, or both
Kinase Inhibitor	acalabrutinib	blood	**Antiandrogen**	Abiraterone	solid
	Ibrutinib	blood		Apaluamide	solid
	Zanubrutibib	blood		Darolutamide	solid
	Copanlisib	blood		enzalutamide	solid
				abarelix	Solid
			Gonadotropin-releasing hormone antagonist	degarelix	Solid
				relugolix	Solid

			Estrogen receptor antagonist	elacestrant	Solid
	Duvelisib	blood	**Monoclonal antibody**	Bretuximab	blood
	idelalisib	blood		Inotuzumab ozogamicin	blood
	Pemigatinib	blood		Polatuzumab	blood
	Everolimus	Solid organ		Moxetumomab	blood
	Abemaciclib	solid organ		Blinatumomab	blood
	Palbociclib	solid organ		Bosutinib	blood
	Ribociclib succinate +/- letrozole	solid organ		Fedratinib	blood
				Gilteritinib	blood
	Afatinib	solid organ		midostaurin	blood
	Dacomitinib	solid organ		Ponatinib	blood
	Necitumumab	solid organ		Ruxolitinib	blood
	Nertinib	solid organ		Daratumumab	blood
	Osimertinib	solid organ		Isatuximab	blood
	Vandetanib	solid organ		Elotuzumab	blood
	Alectinib	solid organ		Obinutuzumab	blood
	Brigatinib	solid organ		ofatumumab	blood
	Ceritinib	solid organ		Ado-trastuzumab	solid
	Lorlatinib	solid organ		Enfortumab	solid
	Alpelisib	solid organ		Fam-trastuzumab	solid
	Avapritinib	solid organ		Sacituzumab	solid
	Olaratumab	solid organ		Pertuzumab	solid
	Axitinib	solid organ		Atezolizumab	solid
	Bevacizumab	solid organ		Avelumab	solid
	Lenvatinib	solid organ		Cemiplimab	solid
	Pazopanib	solid organ		Durvalumab	solid
	Ramucirumab	solid organ		Ipilimumab	solid
	Regorafenib	solid organ		Nivolumab	solid
	Ziv-aflibercept	solid organ		Pembrolizumab	solid
	Binimetinib	solid organ		Tucatinib	solid
	Cobimetinib	solid organ		Pexidartinib	solid
	Trametinib	solid organ		Dinutuximab	solid
	Dabrafenib	solid organ		sipuleucel	solid

	asciminib	Blood		tafasitamab	Blood
	Cabozantinib s-malate	Solid		amivantamab	Solid
	capivasertib	solid		tebentafusp	Solid
	Capmatinib	solid		Belantamab mafodotin	Blood
	furquintinib	Solid		elranatamab	Blood
	futibatnib	solid		epcoritamab	blood
	infigratinib	Solid		Glofitamab	Blood
	mobocertinib	Solid		loncastuximomab	Blood
	momelotinib	Blood		Mirvetuximab soravtansine	solid
	pacritinib	blood		mogamulizumab	Blood
	pirtobrutinib	Blood		mosunetuzumab	solid
	pralsetinib	Solid		naxitamab	Blood
	Quizartinib dihydrochloride	Blood		talquetamab	blood
	repotrectinib	both		tarlatamab	Solid
	ripretinib	solid		teclistamab	Blood
	selpercatinib	Solid		tisotumab	Solid
	tepotinib	Solid		margetuximab	Solid
	Selumetinib	Solid		tremelimumab	Both
	tivozanib	solid		siltuximab	Blood
	umbralisib	Blood		Dostarlimab	Solid
	tovorafenib	Solid		retifanlimab	Solid
	Sirolimus protein bound	Solid		torifanlimab	solid
	Encorafenib	solid organ	CAR-T Cell	Brexucabtagene autoleucel	Blood
	Entrctinib	solid organ		Ciltacabtagene autoleucel	Blood
	Larotrectinib	solid organ		Idecabtagene vicleucel	blood
	Erdafitinib	solid organ		lisocabtagene	Blood
	Crizotinib	both	**Enzyme**	Asparaginase	blood
	vemurafenib	both		calaspargase	blood
			IDH1	Ivosidenib	blood
				olutasidenib	Blood

			IDH2	Elotuzumab	blood
				enasidenib	Blood
			Hedgehog pathway inhibitor	glasdegib	blood
				Sonidegib	solid
KRAS Inhibitor	adagrasib	Solid		vismodegib	solid
	sotorasib	Solid	**PARB inhibitor**	Niraprib	solid
CAR-T Immunotherapy	Axicabtagene ciloleucel	blood			
	Tisagenlecleucel	blood			
Alkylating Agent	Altretamine	Solid	**Antimetabolite**	pralatrexate	Blood
	Bendamustine	Both		trifluride/tipiracil	Solid
	lurbinectedin	Solid	**Taxane derivative**	cabazitaxel	Solid
Miscellaneous	travectedin	Solid		Olaparib	solid
	venetoclax	blood		Rucaparib	solid
	selinexor	blood		talazoparib	solid
	tagraofusp	solid	**Histone methyltransferase inhibitor**	tazemetostat	solid
				belinostat	Blood
				panobinostat	Blood
				romidepsin	Blood
	pomalidomide	both	**Proteasome inhibitor**	Carflizomib	solid
	Talimogene laherparepvec	solid		ixazomib	solid
	Ingenol mebutate	Solid			
	masoprocol	Solid			
	tirbanibulin	Solid			
	belzutifan	Solid			
	omacetaxine	Blood			
	eflornithine	solid			
	imetelstat	blood			
	nirogacestat	Solid			
	lifileucel	Solid			
	nadofaragene	solid			
	Ropeginterferon alfa 2b	Blood			

Antimicrotubula	eribulin	Solid			
Older Antineoplastic Agents					
Drug Class	**Drug**	**Blood, solid, or both**	**Drug Class**	**Drug**	**Blood, solid, or both**
Kinase inhibitor	dasatinib	both	**Retinoic derivatives**	bexarotene	blood
				alitretinoin	solid
	erlotinib	solid		tretinoin	blood
	gefitinib	solid	**Antiandrogen**	Biclutamide	solid
	imatinib	both		flutamide	solid
	lapatinib	solid		nilutamide	solid
				testolactone	Solid
	nilotinib	both	**Antibiotic**	Bleomycin	both
	sorafenib	solid		dactinomycin	solid
	temsirolimus	solid		mitomycin	solid
				plicamycin	Solid
Monoclonal antibody	alemtuzumab	blood	**Alkylating agent**	busulfan	blood
	bevacizumab	solid		carboplatin	both
	cetuximab	solid		carmustine	both
	gemtuzumab ozogamicin	blood		chlorabucil	blood
	panitumumab	solid		cisplatin	both
	rituximab	blood		cyclophosphamide	both
	trastuzumab	solid		dacarbazine	both
Topoisomerase 1 inhibitor	Irinotecan	solid		estramustine	solid
	topotecan	both		ifosfamide	both
Topoisomerase 2 inhibitor	Daunorubicin	blood		mechlorethamine	blood
	Daunorubicin/cytarabine	blood		melphalan	both
	Doxorubicin	both		oxaliplatin	both
	Epirubicin	both		procarbazine	both
	Etoposide	both		streptozocin	solid
	Etoposide phosphate	solid		temozolomide	both
	Idarubicin	blood		Lomustine	Solid
	Mitoxantrone	blood		thiotepa	Blood
	Valrubicin	solid	**Taxane derivative**	docetaxel	solid

	Teniposide	blood		paclitaxel	solid
			Estrogen receptor antagonist	fluvestrant	solid
Aromatase inhibitor	Anastrozole	solid		tamoxifen	solid
	exemestane	solid		toremifene	solid
	letrozole	solid	**Immunomodulators**	Peginterferon alfa-2a	Blood
				aldesleukin	Solid
			Antineogenisis inhibitor	lenalidomide	blood
				sunitinib	solid
Antimetabolite	Azacitidine	blood	**Vinca Alkaloid**	Vinblastine	both
	capecitabine	solid		Vincristine	blood
	cladribine	blood		Vinorelbine	both
	clofarabine	blood	**Histone Deacetylase Inhibitor (HDAC)**	vorinostat	Blood
	cytarabine	blood	**Misc.**	aminolaevulinic acid	solid
	Daunorubicin/cytarabine	blood		arsenic trioxide	blood
	decitabine	blood		BCG live	solid
	floxuridine	Solid		bortezomib	blood
	fludarabine	blood			
	fluorouracil	solid		ixabepilone	solid
	gemcitabine	both		megestrol	solid
	mercaptopurine	blood		mitotane	solid
	nelarabine	blood		pegaspargase	blood
	pemetrexed	solid		Nogapendekin alfa inbakicept	solid
	pentostatin	blood		Methyl aminolevulinate	Solid
	thioguanine	blood		methoxsalen	Blood
	methotrexate	both		porfimer	Solid
				Interferon alfa-2a recomb	Blood
				Interferon alfa-2a recomb	Blood