Washington State Health Care Authority

Oncology Agents: BRAF Kinase Inhibitors - Oral

Medical policy no. 21.53.20-1 Effective Date: 2/1/2026

Related medical policies:

Policy Number	Policy Name
N/A	

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
dabrafenib (Tafinlar) vemurafenib (Zelboraf) tovorafenib (Ojemda) encorafenib (Braftovi)	**BRAF Kinase Inhibitors** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in Non-Clinical Policy No 0001 (NC-001). If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Anaplastic thyroid cancer dabrafenib (Tafinlar)	Dabrafenib (Tafinlar) may be approved when all the following documented criteria are met: 1. Prescribed by, or in consultation with an oncologist; **AND** 2. Dabrafenib (Tafinlar) will be used in combination with trametinib (Mekinist), but will not be used with any other oncolytic medication; **AND** 3. Diagnosis of anaplastic thyroid cancer; **AND** 4. Both of the following are met:

	a. Documentation of a BRAF V600E mutation; **AND** b. Documentation that disease is locally advanced or metastatic with no locoregional treatment options (i.e. surgery, radiation); **AND** 5. The patient has not progressed previously on a BRAF-inhibitor If ALL criteria are met, the request will be authorized for **6 months**.
	Criteria (Reauthorization) Dabrafenib (Tafinlar) may be approved when all the following documented criteria are met: 1. Dabrafenib (Tafinlar) will be used in combination with trametinib (Mekinist), but will not be used with any other oncolytic medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**
Colorectal cancer, metastatic encorafenib (Braftovi)	Encorafenib (Braftovi) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with, an oncologist; **AND** 3. Encorafenib (Braftovi) will be used with the following medications, but will not be used with any additional oncolytic medications: a. For first line treatment, encorafenib (Braftovi) must be used in combination with mFOLFOX6 (leucovorin, fluorouracil, and oxaliplatin) and cetuximab (Erbitux); **OR** b. For subsequent line treatment, cetuximab (Erbitux); **AND** 4. Diagnosis of metastatic (stage IV) colorectal cancer; **AND** 5. Documentation of a BRAF V600E mutation**; AND** 6. The patient has not progressed previously on a BRAF-inhibitor If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Encorafenib (Braftovi) may be approved when all the following documented criteria are met: 1. Encorafenib (Braftovi) will be used in combination with the treatments listed in criteria 3 above, but will not be used with any other oncolytic medications; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**

Erdheim-Chester disease vemurafenib (Zelboraf)	Vemurafenib (Zelboraf) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with, an oncologist or hematologist; **AND** 3. Vemurafenib (Zelboraf) will not be used with any other oncolytic treatments for this indication; **AND** 4. Diagnosis of Erdheim-Chester disease; **AND** 5. Documentation of a BRAF V600E mutation If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Vemurafenib (Zelboraf) may be approved when all the following documented criteria are met: 1. Vemurafenib (Zelboraf) will not be used in combination with any other medications for Erdheim-Chester disease; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**
Hairy cell leukemia, relapsed or refractory vemurafenib (Zelboraf)	Vemurafenib (Zelboraf) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation, with an oncologist or hematologist; **AND** 3. Vemurafenib (Zelboraf) will be used with rituximab, but will not be used with any additional oncolytic medications; **AND** 4. Diagnosis of hairy cell leukemia; **AND** 5. All of the following are met: a. Documentation of a BRAF V600E mutation; **AND** b. Documentation that the patient has refractory or relapsed disease after receiving therapy with a purine analog (cladribine or pentostatin); **AND** c. Therapy with a purine analog was initiated less than two years prior to requesting vemurafenib (Zelboraf); **AND** 7. The patient has not progressed previously on a BRAF-inhibitor If ALL criteria are met, a total of **8 weeks of treatment** will be authorized to be used within **6 months**
	Criteria (Reauthorization) Vemurafenib (Zelboraf) for hairy cell leukemia may not be reauthorized
Low grade glioma dabrafenib (Tafinlar) tovorafenib (Ojemda)	Dabrafenib (Tafinlar) and tovorafenib (Ojemda) may be approved when all the following documented criteria are met: 1. Prescribed by, or in consultation with, an oncologist; **AND**

	2. The medication will not be used with another oncolytic medication except: a. Dabrafenib (Tafinlar) will be used in combination with trametinib (Mekinist); **AND** 3. Diagnosis of pediatric low-grade glioma that requires systemic therapy (i.e. cannot be excised surgically); **AND** 4. Patient meets the following criteria; a. For dabrafenib (Tafinlar): i. Documentation of a BRAF V600E mutation; **AND** ii. Dabrafenib plus trametinib will be used as first line systemic therapy; **OR** b. For tovorafenib (Ojemda): i. Documentation of BRAF fusion or rearrangement, or BRAF V600 mutation; **AND** ii. The disease is relapsed or refractory (i.e. disease has progressed on at least one prior systemic therapy); **AND** 5. The patient has not progressed previously on a BRAF-inhibitor; **AND** 6. The patient's weight and height or body surface area is documented If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Dabrafenib (Tafinlar) and tovorafenib (Ojemda) may be approved when all the following documented criteria are met: 1. Patient meets criteria 3 above**; AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**
Melanoma adjuvant, unresectable, or metastatic dabrafenib (Tafinlar) encorafenib (Braftovi) vemurafenib (Zelboraf)	Dabrafenib (Tafinlar), encorafenib (Braftovi), and vemurafenib (Zelboraf) may be approved when all the following documented criteria are met: 1. For encorafenib (Braftovi) and vemurafenib (Zelboraf) patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with, an oncologist; **AND** 3. The requested treatment will not be used concurrently with another oncolytic medication, other than required by criteria 4 and 5 below; **AND** 4. Diagnosis of resectable stage III melanoma and ALL of the following criteria are met: a. The request is for dabrafenib (Tafinlar) to be used in combination with trametinib (Mekinist); **AND**

	b. Dabrafenib (Tafinlar) will be used as adjuvant treatment meaning the patient has undergone complete surgical resection; **AND** c. There has been disease involvement in regional lymph nodes; **OR** 5. Diagnosis of unresectable or metastatic (stage IIIB, IIIC, or IV) melanoma and ONE the following criteria (a,b, or c) is met: a. For dabrafenib (Tafinlar): i. Will be used in combination with trametinib (Mekinist); **OR** ii. May be used as monotherapy if BRAF V600E mutation is documented and provider attests the patient is unable to tolerate trametinib; **OR** b. For encorafenib (Braftovi): i. Will be used in combination with binimetinib (Mektovi); **OR** c. For vemurafenib (Zelboraf): i. Will be used in combination with cobimetinib (Cotellic) with or without atezolizumab (Tecentriq); **OR** ii. May be used as monotherapy if BRAF V600E mutation is documented and provider attests the patient is unable to tolerate cobimetinib; **AND** 6. Documentation of BRAF V600E or V600K mutation**; AND** 7. The patient has not progressed previously on a BRAF-inhibitor If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Dabrafenib (Tafinlar), encorafenib (Braftovi), and vemurafenib (Zelboraf) may be approved when all the following documented criteria are met: 1. Not used in combination with any other oncolytic medications, except those listed in criteria 4 and 5 above; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**
Non-small cell lung cancer, metastatic dabrafenib (Tafinlar) encorafenib (Braftovi)	Dabrafenib (Tafinlar) and encorafenib (Braftovi) may be approved when all the following documented criteria are met: 1. For encorafenib (Braftovi) patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with, an oncologist; **AND** 3. The requested treatment will not be used concurrently with another oncolytic medication other than required by criteria 4 below; **AND**

	4. Diagnosis of metastatic non-small cell lung cancer and ONE of the following criteria is met: a. For dabrafenib (Tafinlar): i. Will be used in combination with trametinib (Mekinist); **OR** ii. May be used as monotherapy in previously treated patients who were unable to tolerate trametinib (provider attestation); **OR** b. For encorafenib (Braftovi): i. Will be used in combination with binimetinib (Mektovi); **AND** 5. Documentation of a BRAF V600E mutation; **AND** 6. The patient has not progressed previously on a BRAF or MEK inhibitor If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Dabrafenib (Tafinlar) and encorafenib (Braftovi) may be approved when all the following documented criteria are met: 1. Not used in combination with any other oncolytic medications, except those listed in criteria 4 above; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**
Solid tumor, unresectable or metastatic dabrafenib (Tafinlar)	Dabrafenib (Tafinlar) may be approved when all the following documented criteria are met: 1. Patient is 1 year of age or older; **AND** 2. Prescribed by, or in consultation with, an oncologist; **AND** 3. Dabrafenib (Tafinlar) will be used in combination with trametinib (Mekinist), but will not be used with any other oncolytic medication; **AND** 4. Diagnosis of solid tumor that is unresectable or metastatic associated with ONE of the following (**NOTE:** Low-grade glioma is covered per criteria above): a. Biliary tract cancer; **OR** b. High grade glioma; **OR** c. Low grade serous ovarian cancer; **OR** d. Adenocarcinoma of the small intestine; **AND** 5. All of the following criteria are met: a. Documentation of a BRAF V600E mutation; **AND** b. The patient has undergone prior systemic therapy; **AND**

	c. Prior treatments are documented in the medical records and the provider attests that there are no other remaining satisfactory options for the patient**; AND** 6. The patient has not progressed previously on a BRAF-inhibitor; **AND** 7. If used for a pediatric patient (17 years old or younger), weight and height or body surface area is documented If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Dabrafenib (Tafinlar) may be approved when all the following documented criteria are met: 1. Dabrafenib (Tafinlar) will be used in combination with trametinib (Mekinist), but will not be used with any other oncolytic medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., disease has not progressed on therapy] If ALL criteria are met, the request will be authorized for **6 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Braftovi	Melanoma, unresectable or metastatic	450 mg once daily	• 6 capsules per day
	Colorectal cancer, metastatic	300 mg once daily	• 4 capsules per day
	Non-small cell lung cancer, metastatic	450 mg once daily	• 6 capsules per day
Ojemda	Low grade glioma	**Pediatric:** 380mg/m2 once weekly. MAX 600mg per week	• Tablet: 6 per week • Suspension: 24mL (2 bottles) per week
Tafinlar	Anaplastic thyroid carcinoma	150 mg twice daily	• 2 capsules per day
	Melanoma adjuvant, unresectable, or metastatic		
	Non-small cell lung cancer, metastatic		
	Solid tumor, unresectable or metastatic	**Adults:** 150 mg twice daily	• 2 capsules per day • 15 tablets for suspension per day

		Pediatric: Based on weight. MAX 150 mg twice daily	
	Low grade glioma	**Pediatric:** Based on weight. Max 150 mg twice daily	• 2 capsules per day • 15 tablets for suspension per day
Zelboraf	Erdheim-Chester disease	960 mg twice daily	• 8 tablets per day
	Hairy cell leukemia, relapsed or refractory		
	Melanoma, unresectable or metastatic		

Coding:

HCPCS Code	Description
N/A	

Background:

Anaplastic thyroid cancer

Dabrafenib (Tafinlar) is indicated for the treatment of locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation with no satisfactory locoregional treatment options.[2] Tafinlar plus trametinib was evaluated in a non-randomized, open-label trial in patients with rare cancers with the BRAF V600E mutation, including ATC with no standard locoregional treatment options. The primary outcome was overall response rate (ORR) and duration of response (DoR). Participants with ATC (n=36) experienced a 53% overall response rate and a 13.6 median DoR. NCCN guidelines recommend dabrafenib plus trametinib as first line systemic therapy for BRAF mutated disease.

Colorectal cancer, metastatic

Encorafenib (Braftovi) is indicated for the treatment of patients with metastatic colorectal cancer with a BRAF v600E mutation when used in combination with cetuximab and mFOLFOX6.[5] Encorafenib plus cetuximab and mFOLFOX6 was evaluated in randomized, open-label trial in participants with BRAF V600E mutated metastatic colorectal cancer. Participants had no prior systemic treatment, and were randomized into one of three groups: encorafenib plus cetuximab (Group 1), encorafenib plus cetuximab plus mFOLFOX6 (Group 2), or chemotherapy (mFOLFOX 6, FOLFOXIRI, or CAPOX) with or without bevacizumab (Group 3). Group 2 (n=236) demonstrated a statistically significant improvement in overall response rate compared to Group 3 (n=243) (61% vs 40%, respectively). Encorafenib's approval as first line systemic therapy for metastatic colorectal cancer is subject to confirmatory clinical trials, per the FDA's accelerated approval process.

Encorafenib (Braftovi) is also indicated as second-line systemic treatment of patients with metastatic colorectal cancer with a BRAF v600E mutation when used in combination with cetuximab.[5] Encorafenib plus cetuximab was evaluated in a randomized, open-label trial in participants with BRAF v600E mutated metastatic colorectal cancer who had progressed on one or two prior regimens. Participants were randomized to one of three groups: encorafenib plus cetuximab (Group 1), encorafenib plus binimetinib and cetuximab (Group 2), or irinotecan plus cetuximab or FOLFIRI (Group 3). Group 1 (n=220) demonstrated statistically significant improvement in overall survival compared to Group 3 (n=221) (8.4 months vs 5.4 months).

Erdheim-Chester disease

Vemurafenib (Zelboraf) is indicated for the treatment of Erdheim-Chester disease (ECD) with a BRAF v600E mutation.[7] Vemurafenib for the treatment of ECD was evaluated as part of a larger open-label, nonrandomized, study in participants with BRAF V600 mutated nonmelanoma malignancy. The study incorporated data from 22 patients with BRAF V600–mutant ECD, and demonstrated a 54.5% overall response rate, and a 2-year progression-free survival rate of 83%.[6] NCCN guidelines recommend vemurafenib as first line systemic therapy for BRAF mutated disease.

Hairy cell leukemia, relapsed or refractory

Vemurafenib (Zelboraf) is not FDA indicated for relapsed or refractory hairy cell leukemia (HCL), however, evidence suggests vemurafenib plus rituximab can be effective in certain situations. Vemurafenib plus rituximab was evaluated in 30 participants with relapsed or refractory HCL who had experienced a median of 3 prior therapies.[8] Vemurafenib was administered twice daily for 8 weeks. Complete response was observed in 87% of the participants and progression free survival at 37 months was 78%. NCCN recommends vemurafenib plus rituximab in patients with refractory disease after receiving therapy with a purine analog (cladribine or pentostatin) or relapsed disease occurred less than 2 years after intitial therapy. If a relapse occurs greater than 2 years after initial treatment, NCCN recommends retreatment with purine analogs.

Low grade glioma

Tovorafenib (Ojemda) is indicated for the treatment of patients 6 months oand older with relapsed or refractory pediatric low-grade glioma (LGG) with BRAF fusion or rearrangement or BRAF V600E mutation.[12] Tovorafenib was evaluated in an open-label, single-arm, clinical trial involving 76 patients (median age 8.5 years) with BRAF alteration and one measurable lesion. All patients had at least one prior systemic treatment. Tovorafenib contributed to a 51% overall response rate (0% complete response rate) with a median duration of response of 13.8 months.[9] Approval for LGG is subject to confirmatory clinical trials, per the FDA's accelerated approval process.

Dabrafenib (Tafinlar) is indicated in combination with trametinib for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.[2] Dabrafenib plus trametinib was evaluated in an open-label trial that included 110 pediatric patients who required first line systemic therapy for LGG.[10] Overall response rate of participants who took dabrafenib plus trametinib was significantly better compared to those receiving carboplatin plus vincristine (46.6% vs 10.8%, respectively, p<0.001). Progression free survival was also improved for participants taking dabrafenib plus trametinib (20.1 months vs 7.4 months, p<0.001).

Melanoma adjuvant, unresectable, or metastatic

Dabrafenib (Tafinlar) is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations.[2] Dabrafenib as a single agent was compared to dacarbazine in this setting (n=250) and demonstrated an improvement in median progression free survival (5.1 months vs 2.7 months, P<0.0001). Additionally, dabrafenib plus trametinib was compared to dabrafenib plus placebo as first-line therapy in patients with unresectable or metastatic melanoma (n=423) in a randomized, double-blind clinical trial. All patients had BRAF V600E or V600K mutated disease. Participants in the dabrafenib plus trametinib group had greater overall survival compared to dabrafenib plus placebo (25.1 months vs. 18.7 months, respectively, p =0.01). Therefore, use of dabrafenib monotherapy is limited to patients who are unable to tolerate trametinib.

Dabrafenib (Tafinlar) is also indicated for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutation following complete resection.[2] Dabrafenib plus trametinib was compared to placebo in a randomized, double-blind trial in 870 patients with stage III melanoma and regional lymph node involvement. All participants underwent complete resection prior to randomization. Dabrafenib plus trametinib achieved fewer relapse events compared to placebo (38% vs 57%, respectively, P<0.0001).

Encorafenib (Braftovi) is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation in combination with binimetinib.[5] Encorafenib plus binimetinib was compared with vemurafenib in a randominzed, open-label clinical trial in 577 participants with unresectable or metastic melanoma. One prior immunotherapy was allowed.[15] Encorafenib plus binimetinib lead to a longer progression free survival compared to vemurafenib (14.9 months vs. 7.3 months, p <0.001). Overall survival was also superior in the encorafenib plus binimetinib group (33.6 months vs 16.9 months).

Vemurafenib (Zelboraf) is indicated for the treatment of patients with unresectable or metastatic melanoma. Vemurafenib was compared to dacarbazine in 675 patients with treatment-naïve unresectable or metastatic melanoma.[7] Overall and progression-free survival were statistically improved in the vemurafenib group compared to the dacarbazine group (OS-13.6 months vs 10.3 months, PFS – 5.3 months vs 1.6 months).[7] Additionally, cobinmetinib (Cotellic) is indicated for the treatment of adults patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation, in combination with vemurafenib (Zelboraf). Cobinmetinib plus vemurafenib was compared to vemurafenib plus placebo in a randomized, double-blind clinical trial in 495 participants. Cobinmetinib plus vemurafenib outperformed vemurafenib plus placebo in progression free survival and overall survival (OS-22.3 months vs 17.4 months, PFS – 12.3 months vs 7.2 months).[16]

Non-small cell lung cancer (NSCLC), metastatic

Dabrafenib (Tafinlar) is indicated for the treatment of patients with metastatic NSCLC with BRAF V600E mutation.[2] Dabrafenib was evaluated in a three-cohort, non-randomized, open-label, clinical trial in participants with BRAF V600E mutated NSCLC (n=171). Cohorts A (dabrafenib only) and B (dabrafenib plus trametinib) progressed on at least one previous platinum-based chemotherapy regimen and cohort C (dabrafenib plus trametinib) had no prior treatment.[17,18] Objective response rates were 27%, 61%, and 61% for cohorts A, B, and C respectively. Therefore, dabrafenib monotherapy is reserved for those who are unable to take trametinib.

Encorafenib (Braftovi) is indicated for the treatment of adult patients with metastatic NSCLC with a BRAFV600E mutation in combination with binimetinib.[5] Encorafenib plus binimetinib was evaluated in an open-label clinical trial is adults 18 years of older who were treatment-naïve or had one prior systemic therapy for metastatic NSCLC (n=98).[19] Participants had an objective response rate of 75% and 46% in the treatment naïve and previously treated groups, respectively.

Solid tumor, unresectable or metastatic

Dabrafenib (Tafinlar) is indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.[2] Dabrafenib was evaluated in a non-randomized, open-label trial in adults with a variety of solid tumors stemming from high grade glioma (HGG), biliary tract cancer, LGG, adenocarcinoma of the small intestines, and low-grade serous ovarian cancer (n=151). Of solid tumor types with an objective response rate greater than 0, values ranged from 33% (HGG) to 80% (low-grade serous ovarian carcinoma).[20] Dabrafenib plus trametinib was also evaluated in a open-label trials in pediatric patients with HGG and other refractory or recurrent solid tumors. An overall response rate of 56% for HGG and 19% for other solid tumors.[2] Approval for this indication is subject to confirmatory clinical trials, per the FDA's accelerated approval process.

References

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2. Product Information: TAFINLAR® oral capsules, tablets for suspension, dabrafenib oral capsules, tablets for suspension. Novartis Pharmaceuticals Corporation, East Hanover, NJ, 2023.
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7. Product Information: ZELBORAF® oral tablets. Genentech, Inc. and Daiichi Sankyo, Inc., San Francisco, CA, 2020
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21. Product Information: Cotellic® tablets. Genentech, Inc., San Francisco, CA, 2023.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
08/13/2025	02/01/2026	21.53.20-1	Approved by DUR Board. New policy created