Talquetamab Monotherapy (biweekly)

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
As monotherapy for the treatment of adult patients with relapsed and refractory (R/R) multiple myeloma (MM), who have received at least three prior therapies including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI) and an anti-cluster of differentiation 38 (anti-CD38) antibody and have demonstrated disease progression on the last therapy.	C90	00914a	01/11/2025

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Talquetamab is administered at a dose of 0.8mg/kg by subcutaneous (SC) injection every two weeks (after the first cycle [the step-up phase]).

The first cycle is a step-up phase, consisting of step-up doses on Days 1, 3, 5 and 7 of 0.01mg/kg, 0.06 mg/kg, 0.4mg/kg and 0.8mg/kg respectively.
The treatment phase begins from Cycle 2; each cycle in the treatment phase is 28 days.

The recommended dosing schedules are shown in Table 1 (Cycle 1 = step-up phase) and Table 2 (Cycle 2 onwards = treatment phase) below.
Treatment should be continued until disease progression or unacceptable toxicity occurs.

Talquetamab should be administered by a healthcare professional with adequately trained medical personnel and appropriate medical equipment to manage severe reactions, including cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

Patients should be instructed to remain within proximity of a healthcare facility and monitored for 48 hours after administration of all doses within the talquetamab step-up phase for signs and symptoms of CRS and ICANS.

Facilities to treat anaphylaxis MUST be present when systemic anti-cancer therapy (SACT) is administered.

Table 1: Dosing schedule for Cycle 1 (step-up phase)

Drug	Description	Day	Dose	Route	Cycle
Talquetamab[a, b]	Step-up phase	1	0.01 mg/kg	SC[e,f]	Cycle 1 only (step-up phase)
		3[c]	0.06 mg/kg	SC[e,f]	
		5[c]	0.4 mg/kg	SC[e,f]	
		7[c]	0.8 mg/kg	SC[e,f]	
		14-day interval between C1 D7 and C2 D1[d]			
	For Treatment phase, see Table 2 below	Once every 2 weeks thereafter[d]	0.8 mg/kg	SC[e,f]	
[a] Dose is based on actual body weight.					
[b] See Table 3 for recommendations on restarting talquetamab after dose delays.					
[c] Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.					
[d] Maintain a minimum of 12 days between biweekly doses.					
[e] Injection volume should not exceed 2mL. Doses requiring greater than 2mL should be divided equally into multiple syringes and injected at sites at least 2cm apart.					
[f] The required volume of talquetamab should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, talquetamab may be injected into the subcutaneous tissue at other sites (e.g., thigh).					

Table 2: Treatment schedule for Cycle 2 onwards (treatment phase)

Drug	Day	Dose	Route	Cycle
Talquetamab[a, b]	1, 15[c]	0.8mg/kg	SC[d,e] (abdomen or thigh)	Every 28 days from cycle 2 onwards.
[a] Dose is based on actual body weight.				
[b] See Table 3 for recommendations on restarting talquetamab after dose delays.				
[c] Maintain a minimum of 12 days between biweekly doses.				
[d] Injection volume should not exceed 2mL. Doses requiring greater than 2mL should be divided equally into multiple syringes and injected at sites at least 2cm apart.				
[e] The required volume of talquetamab should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, talquetamab may be injected into the subcutaneous tissue at other sites (e.g., thigh).				

ELIGIBILITY:

- Indication as above
- ECOG 0-2
- Adequate hepatic, renal and haematologic function

CAUTIONS:

- Active serious infection. Withhold treatment until infection resolves.
- Vaccination with live virus vaccines is not recommended for at least 4 weeks prior to the start of treatment with talquetamab, during treatment, and at least 4 weeks after treatment.
- Patients with poor immune or haematologic reserve

EXCLUSIONS:

- Hypersensitivity to talquetamab or to any of the excipients
- Pregnancy
- Breastfeeding

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Haematologist working in the area of haematological malignancies.

TESTS:

Baseline tests:

- FBC, renal, liver and bone profile
- Weight
- Pregnancy test for pre-menopausal women
- Immunoglobulin
- Virology screen - Hepatitis B (HBsAg, HBcoreAb) & C, HIV*
  *See Regimen Specific Complications

Regular tests:

- FBC periodically during treatment as clinically indicated. Testing should be more frequent during the step-up phase.
- Renal, liver and bone profile
- Weight
- Immunoglobulin
- Patients should continue to be monitored for signs and symptoms of CRS and ICANS (refer to Tables 6 and 7 for management of CRS and ICANS) *
  *See Regimen Specific Complications

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Dose delays may be required to manage toxicities related to talquetamab. Refer to Table 3 for recommendations on restarting talquetamab after a dose delay.
- See Table 4 for recommended dose modifications for haematological toxicities.
- See Table 5 for recommended dose modification in renal and hepatic toxicity.
- See Tables 6 and 7 for recommended actions for the management of CRS and ICANS.
- See Tables 8 and 9 for recommended dose modifications for neurologic toxicity (excluding ICANS) other adverse reactions.
- Any dose modification should be discussed with a Consultant.

Table 3: Recommendations for restarting therapy with talquetamab after dose delay

Last dose administered	Time from last dose administered	Recommended talquetamab dose*
0.01mg/kg	> 7 days	Restart at 0.01mg/kg
0.06mg/kg	8 – 28 days	Repeat 0.06mg/kg
	> 28 days	Restart at 0.01mg/kg
0.4mg/kg	8 – 35 days	Repeat 0.4mg/kg
	36 – 56 days	Restart at 0.06mg/kg
	> 56 days	Restart at 0.01mg/kg
0.8mg/kg	14 – 35 days	Repeat 0.8mg/kg
	36 – 56 days	Restart at 0.04mg/kg
	> 56 days	Restart at 0.01mg/kg

*Administer pretreatment medicinal products prior to restarting talquetamab. After restarting talquetamab, resume biweekly dosing accordingly.

Haematological:

Table 4: Dose modification of talquetamab in haematological toxicity

Haematologic toxicity	Recommended action
ANC < $0.5x10^9$/L	Withhold talquetamab until ANC ≥ $0.5x10^9$/L
Febrile neutropenia	Withhold talquetamab until ANC ≥ 1 $x10^9$/L and fever resolves.
Platelet count < $25x10^9$/L Platelet count 25 – 50 $x10^9$/L with bleeding	Withhold talquetamab until platelet count is ≥ $25x10^9$/L and no evidence of bleeding.
Haemoglobin < 8 g/dL	Withhold talquetamab until haemoglobin ≥ 8 g/dL.

Renal and Hepatic Impairment:

Table 5: Dose modification of talquetamab in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
No dose adjustment is recommended for patients with mild or moderate renal impairment.	No dose adjustment is recommended for patients with mild hepatic impairment. Limited or no data are available in patients with moderate and severe hepatic impairment.
Renal and hepatic: Recommendations from SmPC for talquetamab	

Management of adverse events:

Cytokine release syndrome (CRS):

CRS should be identified based on clinical presentation. Other causes of fever, hypoxia, and hypotension should be evaluated and treated. If CRS is suspected, talquetamab should be withheld until CRS resolves and should be managed according to the recommendations in Table 6. Supportive therapy for CRS should be administered, which may include intensive care for severe or life-threatening CRS. Laboratory testing should be considered to monitor for disseminated intravascular coagulation (DIC), haematology parameters, as well as pulmonary, cardiac, renal, and hepatic function.

Table 6: Recommendations for management of CRS

Grade[a]	Presenting symptoms	Recommended action	Tocilizumab[b, i]	Corticosteroids[c]
Grade 1	Temperature ≥38 °C[d]	Withhold talquetamab until CRS resolves. Administer pre-treatment medicinal product prior to next dose of talquetamab.	May be considered	Not applicable
Grade 2	Temperature ≥38 °C[d] with either: • Hypotension responsive to fluids and not requiring vasopressors, or • Oxygen requirement of low-flow nasal cannula[e] or blow-by	Withhold talquetamab until CRS resolves. Administer pre-treatment medicinal products prior to next dose of talquetamab. Monitor patient for 48 hours following the next dose of talquetamab.	Administer tocilizumab[c, i] 8 mg/kg intravenously over 1 hour (not to exceed 800 mg). Repeat tocilizumab[i] every 8 hours as needed, if not responsive to intravenous fluids or increasing supplemental oxygen. Limit to a maximum of	If no improvement within 24 hours of starting tocilizumab[i], administer methylprednisolone 1 mg/kg intravenously twice daily, or dexAMETHasone 10 mg intravenously every 6 hours. Continue corticosteroid use until the event is Grade 1 or less, then taper over 3 days.

		Instruct patients to remain within proximity of a healthcare facility during monitoring.	3 doses in a 24-hour period; maximum total of 4 doses.	
Grade 3	Temperature ≥38 °C[d] with either: • Hypotension requiring one vasopressor with or without vasopressin, or • Oxygen requirement of high-flow nasal cannula[e], facemask, non-rebreather mask, or Venturi mask	<u>Duration <48hours</u> Per Grade2. <u>Recurrent or Duration ≥48hours</u> Permanently discontinue talquetamab.	Administer tocilizumab[i] 8mg/kg intravenously over 1 hour (not to exceed 800 mg). Repeat tocilizumab[i] every 8 hours as needed, if not responsive to intravenous fluids or increasing supplemental oxygen. Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses.	If no improvement, administer methylprednisolone 1 mg/kg intravenously twice daily, or dexAMETHasone (e.g., 10 mg intravenously every 6 hours). Continue corticosteroid use until the event is Grade 1 or less, then taper over 3 days.
Grade 4	Temperature ≥38 °C[d] with either: • Hypotension requiring multiple vasopressors (excluding vasopressin), or • Oxygen requirement of positive pressure (e.g., continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, and mechanical ventilation)	Permanently discontinue talquetamab.	Administer tocilizumab[i] 8 mg/kg intravenously over 1 hour (not to exceed 800 mg). Repeat tocilizumab[i] every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen. Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses.	As above, or administer methylprednisolone 1000 mg intravenously per day for 3 days, per physician discretion. If no improvement or if condition worsens, consider alternate immunosuppressants[c].

[a] Based on ASTCT grading for CRS (Lee et al 2019).

[b] Refer to tocilizumab[i] prescribing information for details.

[c] Treat unresponsive CRS per institutional guidelines.
[d] Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anticytokine therapy (e.g., tocilizumab[i] or corticosteroids).
[e] Low-flow nasal cannula is ≤6 L/min, and high-flow nasal cannula is >6 L/min.

Neurologic toxicity, including Immune effector cell-associated neurotoxicity syndrome (ICANS):
At the first sign of neurologic toxicity, including ICANS, talquetamab should be withheld and neurology evaluation should be considered. Other causes of neurologic symptoms should be ruled out. Supportive therapy should be provided, which may include intensive care, for severe or life-threatening ICANS. Management recommendations for ICANS are summarised below in Table 7.

Table 7: Guidelines for management of immune effector cell-associated neurotoxicity syndrome (ICANS)

Grade[a]	Presenting symptoms[b]	Concurrent CRS	No Concurrent CRS
Grade 1	ICE[c] score 7-9 or, depressed level of consciousness[d]: awakens spontaneously.	Management of CRS per Table 6. Monitor neurologic symptoms and consider neurology consultation and evaluation, per physician discretion.	Monitor neurologic symptoms and consider neurology consultation and evaluation, per physician discretion.
		Withhold talquetamab until ICANS resolves. Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis.	
Grade 2	ICE[c] score 3-6 or, depressed level of consciousness[d]: awakens to voice.	Administer tocilizumab[i] per Table 6 for management of CRS. If no improvement after starting tocilizumab[i], administer dexAMETHasone[e] 10 mg intravenously every 6 hours if not already taking other corticosteroids. Continue dexAMETHasone use until resolution to Grade 1 or less, then taper.	Administer dexAMETHasone[e] 10mg intravenously every 6 hours. Continue dexAMETHasone use until resolution to Grade 1 or less, then taper.
		Withhold talquetamab until ICANS resolves. Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. Consider neurology consultation and other specialists for further evaluation, as needed. Monitor patient for 48 hours following the next dose of talquetamab. Instruct patients to remain within proximity of a healthcare facility during monitoring.	

Grade 3	ICE[c] score 0-2 (If ICE score is 0, but the patient is arousable (e.g., awake with global aphasia) and able to perform assessment) or, depressed level of consciousness[d]: awakens only to tactile stimulus, or seizures[d], either: • any clinical seizure, focal or generalised, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local oedema on neuroimaging[d].	Administer tocilizumab[i] per Table 6 for management of CRS. Administer dexAMETHasone[e] 10mg intravenously with the first dose of tocilizumab[i], and repeat dose every 6 hours. Continue dexAMETHasone use until resolution to Grade 1 or less, then taper.	Administer dexAMETHasone[e] 10mg intravenously every 6 hours. Continue dexAMETHasone use until resolution to Grade 1 or less, then taper.
		Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. Consider neurology consultation and other specialists for further evaluation, as needed. <u>First Occurrence</u>: Withhold talquetamab until ICANS resolves. Monitor patient for 48 hours following the next dose of talquetamab. Instruct patients to remain within proximity of a healthcare facility during monitoring. <u>Recurrent</u>: Permanently discontinue talquetamab.	
Grade 4	ICE[c] score 0 (Patient is unarousable and unable to perform ICE assessment) or, depressed level of consciousness[d] either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures[d], either: • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings[d]:	Administer tocilizumab[i] per Table 6 for management of CRS. Administer dexamethasone[e] 10mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade1 or less, then taper. Alternatively, consider administration of methylprednisolone 1000mg per day intravenously with first dose of tocilizumab[i], and continue methylprednisolone 1000 mg per day intravenously for 2 or more days.	Administer dexamethasone[e] 10mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade1 or less, then taper. Alternatively, consider administration of methylprednisolone 1000 mg per day intravenously for 3 days; if improves, then manage as above.

	• deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure/cerebral oedema[d], with signs/symptoms such as: • diffuse cerebral oedema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilloedema, or • Cushing's triad	Permanently discontinue talquetamab. Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis. Consider neurology consultation and other specialists for further evaluation, as needed. In case of raised intracranial pressure/cerebral oedema, refer to institutional guidelines for management.

[a] ASTCT 2019 grading for ICANS.

[b] Management is determined by the most severe event, not attributable to any other cause.

[c] If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, e.g., point to clock, pen, button = 3 points); **Following Commands** (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point; and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.

[d] Attributable to no other cause.

[e] All references to dexAMETHasone administration are dexAMETHasone or equivalent.

Table 8: Recommendations for management of neurologic toxicity (excluding ICANS)

Adverse reactions	Severity[a]	Actions
Neurologic Toxicity[a] (excluding ICANS)	Grade 1	• Withhold talquetamab until neurologic toxicity symptoms resolve or stabilise.[b]
	Grade 2 Grade 3 (First occurrence)	• Withhold talquetamab until neurologic toxicity symptoms improve to Grade1 or less.[b] • Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	• Permanently discontinue talquetamab. • Provide supportive therapy, which may include intensive care

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version4.03.

[b] See Table 3 for recommendations on restarting talquetamab after dose delays.

Table 9: Recommended dose modifications for talquetamab for other adverse events

Adverse reactions	Severity	Actions
Serious infections	All Grades	• Do not administer talquetamab step-up dosing schedule in patients with active infection. • Withhold talquetamab in the step-up phase until infection resolves.
	Grade 3-4	• Withhold talquetamab during the treatment phase until infection improves to Grade2 or better.
Oral toxicity, including weight loss	Toxicity not responding to supportive care	• Interrupt talquetamab until stabilisation or improvement, and consider restarting on modified schedule as follows: ○ If current dose is 0.4mg/kg every week, change to 0.4mg/kg every two weeks ○ If current dose is 0.8mg/kg every two weeks, change to 0.8mg/kg every four weeks
Skin reactions, including nail disorders	Grade 3-4	• Withhold talquetamab until adverse reaction improves to Grade 1 or baseline.
Other non-haematologic adverse reactions[a]	Grade 3-4	• Withhold talquetamab until adverse reaction improves to Grade 1 or baseline.

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), Version 4.03.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting - Available on the NCCP website

Talquetamab: Minimal **(Refer to local policy)**

For information:
Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - Available on the NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - Available on the NCCP website

PREMEDICATIONS:

- The following pre-treatment medicinal products must be administered 1 to 3 hours before each dose of talquetamab **during the step-up phase** to reduce the risk of CRS:
  - Corticosteroid (The SmPC notes oral or intravenous dexamethasone 16 mg or equivalent)
  - Antihistamine (The SmPc notes oral or intravenous diphenhydramine 50mg or equivalent)
  - Antipyretics (The SmPC notes oral or intravenous paracetamol 650mg to 1000mg or equivalent)

- Table 10 below provides details on recommended premedications prior to talquetamab doses.
- Pre-treatment medicinal products should be administered prior to subsequent doses for patients who repeat doses within the talquetamab step-up phase due to dose delays or for patients who experienced CRS (see Table 10 below).

Table 10: Recommended premedications prior to talquetamab doses*

Cycle	Patient requiring pre-medication	Pre-medication*	Administration
1	All patients (Days 1, 3, 5 and 7)	Dexamethasone 20mg PO	60 minutes prior to dose
		Chlorphenamine 10mg IV	60 minutes prior to dose
		Paracetamol 1g PO	60 minutes prior to dose

*For patients who repeat doses within the step-up phase due to dose delays or for patients who experienced CRS, consider extending prophylactic medications to the 2nd cycle at physician discretion.

OTHER SUPPORTIVE CARE:

- Antiviral prophylaxis **(Refer to local policy)**
- Tumour lysis prophylaxis **(Refer to local policy)**
- Anti-bacterial prophylaxis **(Refer to local policy)**
- Anti-fungal prophylaxis **(Refer to local policy)**
- Consider PJP prophylaxis **(Refer to local policy)**
- Immunoglobulin replacement **(Refer to local policy)**
- Mouthcare (may include saliva stimulating agents, steroid mouth wash or consultation with a nutritionist) **(Refer to local policy)**
- Females of reproductive potential should use effective contraception during treatment and for 3 months after the last dose of talquetamab

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics for details.
- **Talquetamab is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions.**

REGIMEN SPECIFIC COMPLICATIONS:

- **Hepatitis B Reactivation:** Patients should be tested for both HBsAg and HBcoreAb as per local policy. If either test is positive, such patients should be treated with anti-viral therapy **(Refer to local infectious disease policy).** These patients should be considered for assessment by hepatology.
- **Cytokine release syndrome (CRS):** CRS, including life-threatening or fatal reactions, may occur in patients receiving talquetamab. Clinical signs and symptoms of CRS may include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, tachycardia and elevated transaminases. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC). Talquetamab therapy should be initiated with step-up phase dosing and pre-treatment medicinal products (corticosteroids, antihistamine, and antipyretics) should be administered prior to each dose of talquetamab during the step-up phase to reduce the risk of CRS. Patients should be monitored following administration accordingly. In patients who experience CRS following their previous dose, pre-treatment medicinal products should be administered prior to the

next talquetamab dose. Patients should be counselled to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, patients should be immediately evaluated for hospitalisation and treatment with supportive care, tocilizumab[i] and/or corticosteroids, should be instituted based on severity. The use of myeloid growth factors, particularly granulocyte macrophage-colony stimulating factor (GM-CSF), should be avoided during CRS. Talquetamab should be withheld until CRS resolves.

- **Neurologic toxicity, including ICANS:** Serious or life-threatening neurologic toxicities, including ICANS have occurred following treatment with talquetamab. ICANS, including fatal reactions, have occurred following treatment with talquetamab. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia. Patients should be monitored for signs and symptoms of neurologic toxicities and treated promptly. Patients should be counselled to seek medical attention should signs or symptoms of neurologic toxicities including ICANS occur. At the first sign of neurologic toxicities including ICANS, the patient should be immediately evaluated, and supportive care should be provided based on severity. Patients who experience Grade 2 or higher ICANS should be instructed to remain within proximity of a healthcare facility and monitored for signs and symptoms for 48 hours following the next dose of talquetamab. For ICANS and other neurologic toxicities, talquetamab should be withheld or discontinued based on severity and management recommendations should be followed as indicated in Table 7. Due to the potential for ICANS, patients should be instructed to avoid driving or operating machines during the step-up phase and for 48 hours after completion of the step-up phase, and in the event of new onset of any neurological symptoms, until symptoms resolve.
- **Oral toxicity:** Oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis occur very commonly following treatment with talquetamab. Patients should be monitored for signs and symptoms of oral toxicity. Patients should be counselled to seek medical attention should signs or symptoms of oral toxicity occur, and supportive care should be provided. Supportive care may include saliva stimulating agents, steroid mouth wash, or consultation with a nutritionist. Talquetamab should be interrupted or less frequent dosing should be considered. Over time, notable weight loss may occur. Weight change should be monitored regularly during therapy. Clinically significant weight loss should be further evaluated. Talquetamab should be interrupted or less frequent dosing should be considered (see Table 9).
- **Skin reactions:** Talquetamab can cause skin reactions including rash, maculo-papular rash, erythema, erythematous rash, as well as nail disorders. Skin reactions, including rash progression, should be monitored for early intervention and treatment with corticosteroids. For Grade 3 or higher, or worsening Grade 1 or 2 rashes, oral steroids should also be administered. For non-rash skin reactions dose modification may be considered. For skin reactions and nail disorders, talquetamab should be withheld based on severity and institutional guidelines should be followed (see Table 9).
- **Influence on driving ability/use of machinery:** Talquetamab has major influence on the ability to drive and use machines. Due to the potential for ICANS, patients receiving talquetamab are at risk of depressed level of consciousness. Patients should be instructed to avoid driving or operating machines during the step-up phase and for 48 hours after completion of the step-up phase, and in the event of new onset of any neurological symptoms, until symptoms resolve.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

COMPANY SUPPORT RESOURCES/Useful Links:

Please note that this is for information only and does not constitute endorsement by the NCCP.

Prescriber Card:
https://assets.hpra.ie/products/Human/40097/b9bee4b0-9a67-4668-b757-7792939f03f5.pdf

Patient Alert Card:
https://assets.hpra.ie/products/Human/40097/2c48c34b-eaac-4d24-b614-5f4efb3b4c47.pdf

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2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Antiemesis Version 1.2025 – March 27, 2025. Accessed May 2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf
3. Talquetamab (Talvey®) Summary of Product Characteristics. Last updated: 28/06/2024. Accessed: July 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1	29/10/2025		Dr. Patrick Hayden

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

[i] This is an unlicensed indication for the use of tocilizumab in Ireland. Patients should be informed of this and consented to treatment in line with the hospital's policy on the use of unlicensed medication and unlicensed or "off label" indications. Prescribers should be fully aware of their responsibility in communicating any relevant information to the patient and also ensuring that the unlicensed or "off label" indication has been acknowledged by the hospital's Drugs and Therapeutics Committee, or equivalent, in line with hospital policy