TALIMOGENE LAHERPAREPVEC (Imlygic) (gene therapy)

INDICATION (ICD10) C43

Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (TAL1)

1. Talimogene laherparepvec monotherapy for treating unresectable stage IIIb, stage IIIc or stage IVM1a **metastatic melanoma.** Normal serum LDH. Cutaneous, subcutaneous or nodal deposit(s) of melanoma which is/are suitable for direct injection but is/are not surgically resectable. No bone, brain, lung or any other visceral secondaries. (TA410)

REGIMEN

Gene therapy (Amgen approval required, specific training required see SOP)
TALIMOGENE LAHERPAREPVEC intralesional injection

Talimogene laherparepvec is provided in single use vials of 1mL each in two different concentrations:
• 10^6 (1 million) PFU/mL - For initial dose only.
• 10^8 (100 million) PFU/mL - For all subsequent doses.
The total injection volume for each treatment visit should be up to a maximum of 4mL. The initial recommended dose is up to a maximum of 4mL of Talimogene laherparepvec at a concentration of 10^6 (1 million) PFU/mL Subsequent doses should be administered up to 4mL of Talimogene laherparepvec at a concentration of 10^8 (100 million) PFU/mL

Treatment visit	Treatment interval	Maximum total injection volume	Dose concentrations	Prioritisation of lesions to be injected
Initial	-	Up to 4mL	10^6 (1 million) PFU/mL	• Inject largest lesion(s) first. • Prioritise injection of remaining lesions based on lesion size until maximum injection volume is reached.
Second	3 weeks after initial treatment	Up to 4mL	10^8 (100 million) PFU/mL	• First inject any new lesions (lesions that may have developed since initial treatment). • Prioritise injection of remaining lesions based on lesion size until maximum injection volume is reached.
All subsequent treatment visits (including re-initiation)	2 weeks after previous treatment	Up to 4mL	10^8 (100 million) PFU/mL	• First inject any new lesions (lesions that may have developed since previous treatment). • Prioritise injection of remaining lesions based on lesion size until maximum injection volume is reached.

Lesion size (longest dimension)	Talimogene laherparepvec injection volume
>5cm	up to 4mL
>2.5cm to 5cm	up to 2mL
>1.5cm to 2.5cm	up to 1mL
>0.5cm to 1.5cm	up to 0.5mL
≤0.5cm	up to 0.1mL

ANTI-EMETICS
None required

CONCURRENT MEDICATION REQUIRED
None required

INVESTIGATIONS
Blood results required before SACT administration
FBC, U&E and LFTs every cycle
Neutrophils x 10^9/L ≥1.0
Platelets x 10^9/L ≥100
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Talimogene laherparepvec	Cellulitis and impaired healing at injection site Herpetic infections – new lesions should be swabbed and sent to Amgen Plasmacytoma Influenza like symptoms

INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
(not exhaustive list check SPC/BNF/Stockleys)

Talimogene laherparepvec	-

DOSE MODIFICATIONS
None

REFERENCES
1. NICE TA