



Discussion on Novel IntraVesical Therapies | Transition from Clinical Operations to Operational Considerations

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Different Agents and Routes

intraVESICAL

BCG

Nogapendekin-alfa

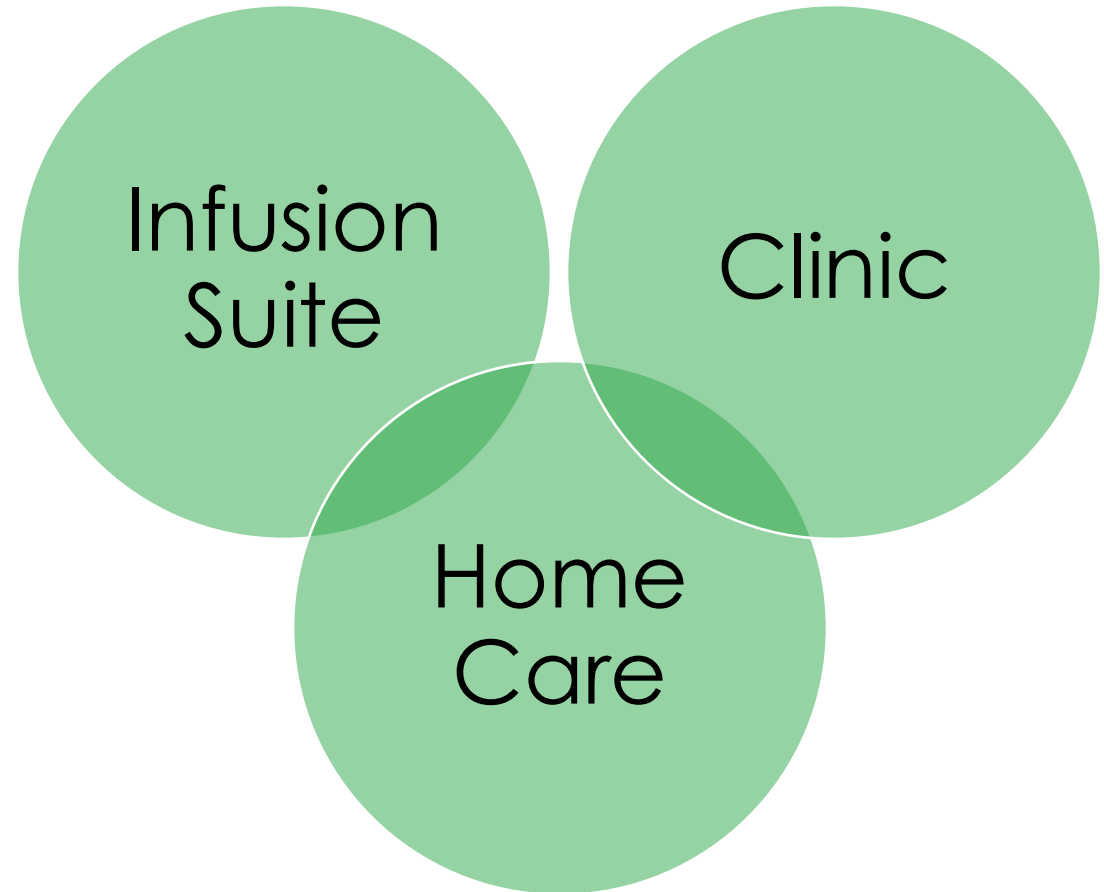
Nadofaragene

intraVENOUS

Pembrolizumab

subCUTANEOUS

???



Clinical Considerations

Dosing

Every weekly vs every 3 weeks vs every 3 months

Clinical Clearance

Urinalysis 24-48 hrs prior to prevent waste

Pre-medications

Oxybutynin pre-medication

Patient Education

Monitoring

CMP?



Operational Considerations

Procurement

Dropship

Expected time of arrival

Storage considerations

Freezer for nadofaragene firadenovec-vncg

In a freezer $\leq -60^{\circ}\text{C}$ until expiry date printed on the carton

In a freezer between -25°C to -15°C up to 3 months

Refrigerator ($2 - 8^{\circ}\text{C}$) for pembrolizumab, BCG, and nogapendekin alfa inbakicept-pmIn

Compounding and hazardous handling at administration

BCG terminal cleaning

Biohazard handling for viral vector

Inventory management



Financial Considerations

Insurance Restrictions

Site of care

Guideline Recommendations

Similar place in therapy for BCG unresponsive/intolerant patients



Future State

Additional agents

Immunotherapies (nivolumab, atezolizumab)

Novel gene therapies

Combinations of agents

Immunotherapy combinations

Nadofaragene +/- chemotherapy +/- immunotherapy

Where to next?

Critical assessment of efficacy outcomes

Sequencing of regimens

Head to head studies

