BiTE Therapy in the Community

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THEDACARE REGIONAL CANCER CENTER



DISCLOSURES

• None





BiTE Therapies

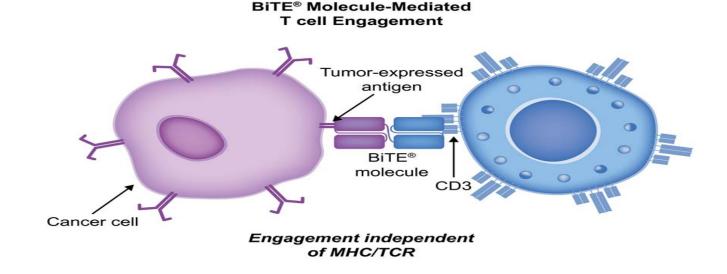
Drug	Disease	Route	Tumor Antigen Target	FDA Approval
Elranatamab	MM	SQ	BCMA	8/14/23
Epcoritamab	DLBCL FL	SQ	CD20	5/19/23
Glofitamab	DLBCL	IVPB	CD20	6/15/23
Mosunetuzumab	FL	IVPB	CD20	12/22/22
Talquetamab	MM	SQ	GPRC5D	8/9/23
Tarlatamab	SCLC	IVPB	DLL3	5/16/24
Tebentafusp	Uveal melanoma	IVPB	gp100/HLA-A*02:01 complex	1/25/22
Teclistamab	MM	SQ	BCMA	10/25/22

FL: Follicular lymphoma, DLBCL: Diffuse large B cell lymphoma, MM: Multiple myeloma, SCLC: small cell lung cancer



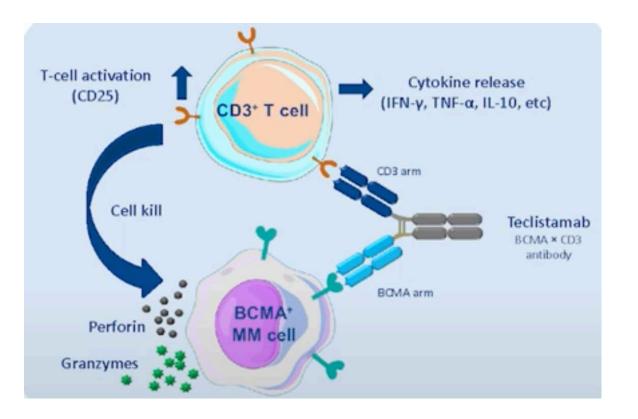
BiTE therapy: Mechanism of action

- BiTE stands for <u>bispecific T</u> cell <u>engager</u>
- Bispecific antibody that binds a tumor associated antigen on tumor cells to the surface molecule on T-cell. This then induces tumor lysis



American Cancer Society, 2020 https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.32909

BiTE therapy



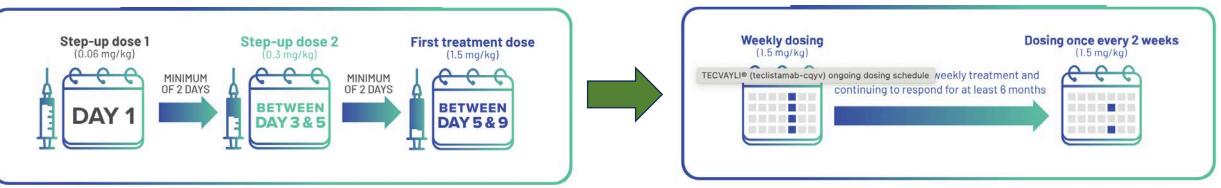
• Toxicities

- Cytokine release syndrome (CRS)
- Immune effector cell associated neurotoxicity syndrome (ICANS)/neurotoxicity
- Infections
- Cytopenia
- Tumor flare
- Talquetamab: dermatological toxicities, nail disorders

Step-up Dosing



- Administration of BiTE therapy in given in a step up dosing schedule in an effort to limit toxicity
 - Pre-medications are given: dexamethasone, Tylenol and benadryl
- For majority of BiTE therapies the step-up doses are given in the hospital and monitored for 24-48 hours.
 - Epcoritamab and Mosunetuzumab for follicular lymphoma can be given outpatient
 - Example below of teclistamab step up dosing





Cytokine Release Syndrome (CRS)

- Signs and symptoms
 - Fever
 - Chills
 - Headache
 - Myalgias, arthralgia
 - Malaise
 - Anorexia
 - Skin rash
 - Hypotension, tachycardia
 - Hypoxia, tachypnea
 - Multiorgan failure
 - Disseminated intravascular coagulation (DIC)



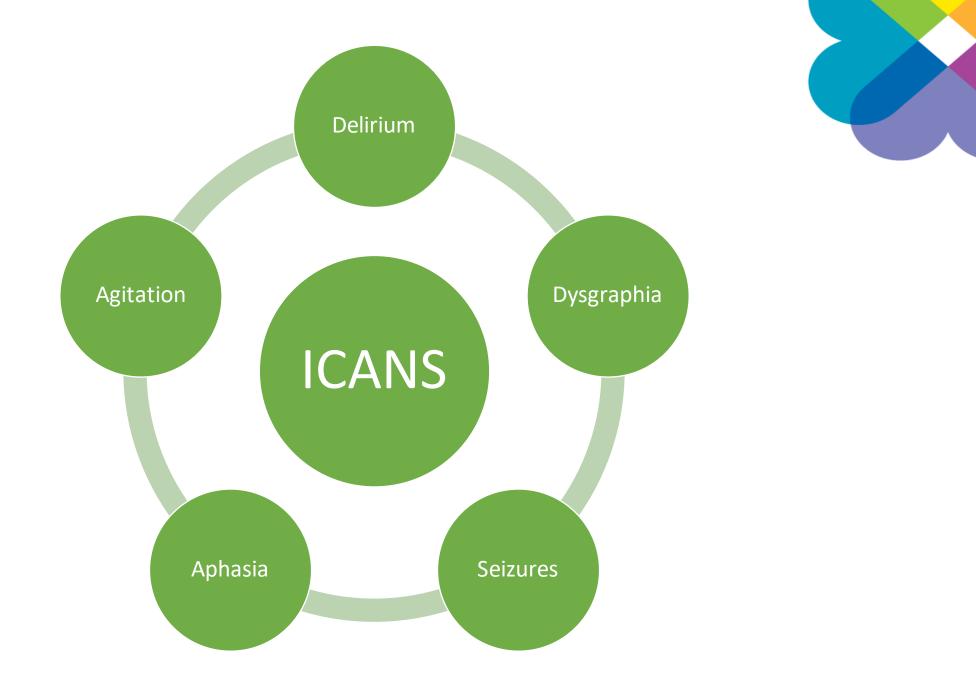


ASTCT CRS grading

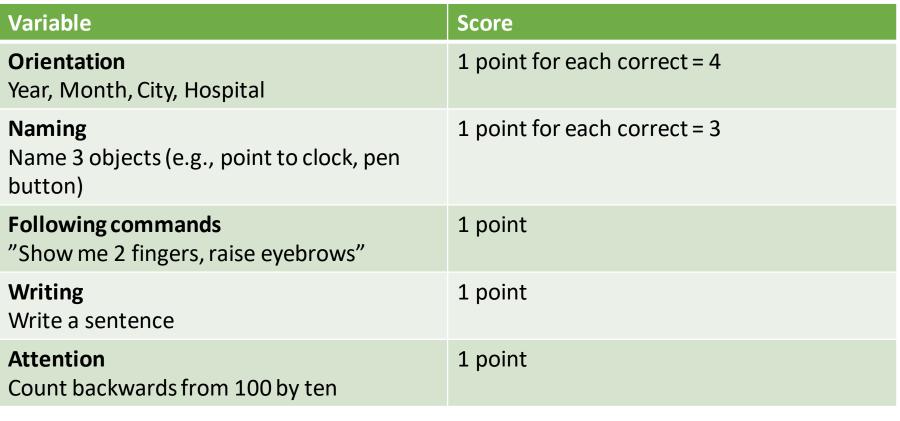
CRS parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever*	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C
With				
Hypotension	None	Not requiring vasopressors	Requiring a vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
And/or†				
Hypoxia	None	Requiring low-flow nasal cannula or blow-by	Requiring high-flow nasal cannula, face mask, non- rebreather mask, or venturi mask	Requiring positive press CPAP, BiPAP, intubation mechanical ventilation)

- Management of CRS
 - Tocilizumab (IL-6 inhibitor)
 - Steroids
 - Supportive care

Lee DW, et al. ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. Biol Blood Marrow Transplant. 2019 Apr;25(4):625-638. doi: 10.1016/j.bbmt.2018.12.758. Epub 2018 Dec 25. PMID: 30592986.



ICE Score



Scoring:

10: no impairment	0-2: grade 3
7-9: grade 1	0: Patient unarousable, grade 4
3-6: grade 2	





ASTCT ICANS Consensus Grading

Neurotoxicity domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE score*	7–9	3–6	0–2	0 (patient is unarousable)
Depressed level of consciousness†	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma
Seizure	N/A	N/A	Any clinical seizure focal or generalized that resolves rapidly or non- convulsive seizures on EEG that resolve with intervention	Life-threatening prolonged seizure (>5 min), repetitive clinical or electrical seizures without return to baseline in between
Motor findings‡	N/A	N/A	N/A	Deep focal motor weakness such as hemiparesis or paraparesis
Elevated ICP/ cerebral edema	N/A	N/A	Focal/local edema on neuroimaging§	Diffuse cerebral edema on neuroimaging, decerebrate or decorticate posturing, cranial nerve VI palsy, papilledema, or Cushing's triad

Management of ICANS

Manual Annual attack

- Aggressive supportive care
- Steroids, if not responsive to steroids consider Anakinra and other therapies
- If there is concurrent CRS, consider tocilizumab

Prevalence of CRS and ICANS

Teclistamab-MAJESTIC-1

- CRS: any grade 72%, G3-4: 0.6% (cycle 2 and beyond 3.6% CRS all G1)
- Time to CRS: 2 days and lasts 2 days
- ICANS any grade: 14.5%, G 3-4: 0.6%

Talquetamab- MonumenTAL-1

- CRS: 80% G1-2, G3-4:0%
- ICANS: 9%

Mosunetuzumab-GO29781

- CRS for FL 44%, majority grade 1-2.
- ICANS: 1% all G1

Epcoritamab-EPCORE NHL-1

- CRS: 50% G1-2, G3-4: 2.5%
- ICANS: 6.4% G1-2, 0.6% G3-4

Infections

- Prevention is key
 - Antiviral prophylaxis
 - PJP prophylaxis
 - Bacterial prophylaxis
 - Fungal prophylaxis (if ANC < 500)
 - IVIG for low IgG
- Vaccinations
 - Ensure patients are update on standard vaccinations



Risk of Infections with BiTE therapies

Drug	Disease	Neutropenia	Lymphopenia	Serio	usinfea	ctions
Drug	Disease	(≥ grade 3)	(≥ grade 3)	All	≥G3	Fatal
Elranatamab	MM	51%	84%	42%	31%	7%
Epcoritamab	DLBCL	32%	77%	15%	14%	1.3%
Glofitamab	DLBCL	27%	-	38%	-	-
Mosunetuzumab	FL	38%	92%	17%	14%	0.9%
Talquetamab	MM	35%	80%	16%	17%	1.5%
Teclistamab	MM	56%	84%	30%	35%	4.2%

CHALLENGES

- Lack of familiarity of BiTE therapy as a health system
- Knowledge of toxicity management among oncology practice, subspecialty services, RNs, pharmacists
- Turnover of staffing
- Prolonged distance to healthcare facility



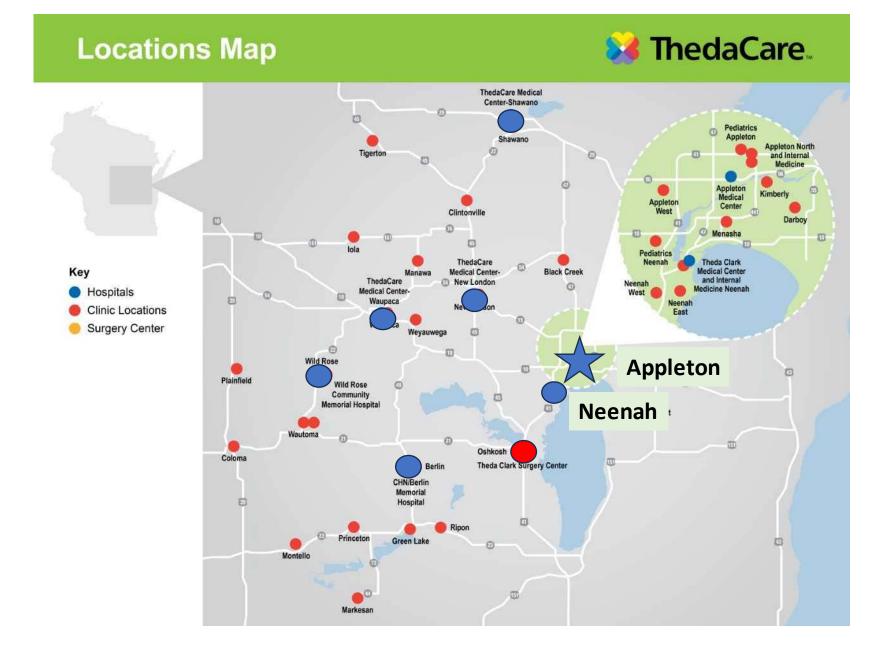
• Lack of an in person oncology provider overnight





Instituting BITE Therapy in the Community

- Education
 - Hematology/oncology providers, hematology navigators, ER providers (Appleton and satellite ER), intensivists, hospitalists, PCP, inpatient and outpatient pharmacists, inpatient and outpatient nursing and triage line staff
 - Developed a learning module which is required
 - Individual presentations with each department
- Creating order sets
 - Easy access to CRS and ICANS grading table
 - Prespecified dosing for dexamethasone and tocilizumab
- Creating a Best Practice Advisory (BPA)
 - Creating awareness of when a BITE patient enters the hospital







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Patient example

- Mr. Luigi is a 75 year old male with IgG kappa multiple myeloma who is penta-refractory and had disease progression after CAR-T therapy
 - Comes to Appleton for evaluation of BiTE therapy

Initial Outpatient Evaluation for BiTE therapy

- Inquire where patient lives and do they have care giver support
- Make sure patient has at least a thermometer.
 - Ideal to have BP cuff and pulse ox as well
- Baseline labs with CMV, hepatitis B/C status, IgG
- Provide wallet card



- Patient is admitted for step up dosing. There are different dosing schedules and we are mainly following package insert. Typically admitting for 48 hours after each step up dosing at our Appleton location.
 - Place new admission order set for BiTE therapy





Labs

CBC/Complete Blood Ct w/Diff

Routine, DAILY, First occurrence tomorrow at 0630, Until Specified Blood Release to patient. All results release immediately, except the following will release Immediate

Basic Metabolic Panel ()

Routine, DAILY, First occurrence tomorrow at 0630, Until Specified Blood Release to patient. All results release immediately, except the following will release Immediate Includes BUN, CREATININE, GLUCOSE, NA, K. CL. CALCIUM and TOTAL CO2.

Liver Panel

Routine, DAILY, First occurrence tomorrow at 0630, Until Specified Blood Release to patient. All results release immediately, except the following will release Immediate Includes a Total Protein,Albumin,Alkaline Phosphotase,Direct and Total Bilirubin, SG

Ferritin

Routine, DAILY, First occurrence tomorrow at 0630, Until Specified Blood Release to patient. All results release immediately, except the following will release Immediate

ESR (Sed Rate)

Routine, DAILY, First occurrence tomorrow at 0630, Until Specified Blood Release to patient. All results release immediately, except the following will release Immediate

C Reactive Protein, Blood

Routine, DAILY, First occurrence tomorrow at 0630, Until Specified Blood Release to patient. All results release immediately, except the following will release Immediate CRP is a general marker for infection and inflamation.

🗸 LDH, Serum

Routine, DAILY, First occurrence tomorrow at 0630, Until S Blood

Release to patient. All results release immediately, except Immediate

Prothrombin Time

Routine, DAILY, First occurrence tomorrow at 0630, Until S Blood Release to patient. All results release immediately, except s

Immediate

Activated Partial Thromboplastin Time

Routine, DAILY, First occurrence tomorrow at 0630, Until S Blood

Release to patient. All results release immediately, except Immediate

Fibrinogen

Routine, DAILY, First occurrence tomorrow at 0630, Until S Blood

Release to patient. All results release immediately, except Immediate

D Dimer, Quantitative

Routine, DAILY, First occurrence tomorrow at 0630, Until S Blood

Release to patient. All results release immediately, except Immediate





- Obtain baseline ICE score
- Link to ICE score sheets are in new admission order set

🔽 ICE Score 🕧

Routine, UNTIL DISCONTINUED, today at 1733, For 1 occurrence, ICE Score can be found at the following link: https://sharewell.thedacare.org/clinical/Cancer%20Business%20Line/MedicalOncology/_layouts/15/WopiFrame2.aspx?sourcedoc=%7B91D3A679-CEDC-4331-B555-32A432986827%7D&file=ICE%20SCORE.docx&action=default&IsList=1&ListId=%7BE8AB4721-BA3F-436A-9317-4E4CDDB659E6%7D&ListItemId=341

 Place paper copy of completed form in patient's chart and document the result as a flowsheet entry using the flowsheet template "ICE Neuro"

• ICE SCORE Nursing Communication

Please ensure an ICE score is obtained and documented as a flowsheet encounter by physician OR nursing staff at baseline. Routine, UNTIL DISCONTINUED, today at 1733, For 1 occurrence, Please obtain an ICE score at baseline for each patient. Please print the ICE score template using the "ICE Score" link above on ShareWell. Patient receives a point for each correct answer. A completed paper copy of the ICE score should be placed in the patient's chart. The ICE score also needs to be documented as a flowsheet entry using the flowsheet template "ICE Neuro." Optional for providers: Once the entry is completed in flowsheets, please create a separate note using the .dotphrase ".ICESCORE." The entries from the flowsheet will auto-populate.

- ICE SCORE Nursing Flow Sheet
 - Enter in the comments section which specific questions were incorrect

Flowsheets		?	DE	Ξ
📙 <u>F</u> ile 📮 Add <u>R</u> ows 👫	► LDA Avatar 🔻 ଲ‡ Add Col n‡n Insert Col ᢞ Device Data 🖑 Hide Device Data 💌 må Last Filed 🔹 Reg Doc 🔝 Graph 💌 More 🔻			
Vitals/Pain Home Infus	sion I/O CT PPV/Pain (RETIRED) Daily Cares/Safety Head to Toe ICE Neuro 🗸 ICE Neuro	,o	8	E.
Search (Alt+C Hide All Show All	Expanded Im 5m View All 1/31/24 <t< td=""><td>t</td><td>ţ</td><td></td></t<>	t	ţ	
ICE Neurologi 🗹	ThedaCare Region 1=Identifies 1 1/31/2024 3=Identifies 3 1700 4=Identifies All 4		X	
	ICE Neurological Assessment 0=Identifies None ICE Orienta 3 > ICE Naming Incorrect location ICE Followi Incorrect location ICE Writing Incorrect location ICE Attention 3 (P) ICE Score Taken by: Ebben, Leah, PA-C	- *		
	Ability to name Month, Year, City, and Hospital (Theda	— ♠ Care)		



• We have specific parameters as part of the order set of when to page the on call oncology provider

Please notify provider immediately for any of the following Routine, UNTIL DISCONTINUED, today at 1733, For 1 occurrence Temperature greater than: 100.4 Systolic BP less than: 90 Diastolic BP less than: 60 SpO2 less than: 91

Please notify provider immediately with any mental status change/abnormal ICE score Routine, UNTIL DISCONTINUED, today at 1733, For 1 occurrence, Please notify provider immediately with any mental status change/abnormal ICE score



- Nursing pages on call oncologist for any change in vitals or neurological status
- Overnight we will be dependent on our hospitalist service if there is a change in clinical status and patient needs to be evaluated.



Hospital Discharge

- After 48 hours, if no signs of CRS or ICANS, patient can discharged
- Provide discharge instructs/triage phone number to call for any concerns of CRS/ICANS
 - Some institutions may decide to discharge with home dexamethasone

.BITEDISCHARGE DOTPHRASE

BiTE Therapy Discharge Instructions

Cytokine release syndrome (CRS) and neurological changes can be a common side effect of BiTE therapy medication.

CRS may occur as the body quickly releases cytokines. Your immune system and the T cells attacking the cancer cells make cytokines. The released cytokines can cause symptoms such as fever, chills, fatigue, dizziness, and headache. The symptoms can be mild, or in some cases severe or life-threatening.

Neurologic changes can also occur. Common changes may include confusion, tremors/shaking, seizures, word-finding difficulty, responding slowly when talking to others, excessive sleepiness or trouble staying awake.

These side effects, and the complete list below, are not permanent. It is very important that if you start to experience any of the symptoms listed, you or your caregiver seek immediate care or call our clinic (920) 364-3600 right away.

CALL 911 RIGHT AWAY FOR:

- Sudden shortness of breath
- Chest pain
- Bleeding that will not stop

CALL YOUR DOCTOR FOR ANY OF THE FOLLOWING:

- Oral (mouth) temperature more than 100.4° F or 38°C
- Chills or shaking with or without fever
- Increased fatigue (tiredness) or weakness
- Confusion, tremor or headache that will not go away
- Dizziness, lightheadedness, falls or difficulty walking
- Numbness or tingling in your arms and/or legs
- Shortness of breath, trouble breathing
- Fast or irregular heart rate, chest pain
- Nausea or vomiting that is not controlled with medication
- 3 episodes or more of diarrhea in a day with/without belly pain that will not go away



- After 24 hours after discharge, patient calls triage line that they have a fever and rigors
- This BPA will fire on anyone who opens the chart of someone on BiTE therapy (triage, ER)

iportant (1)		
treated. Please direct patient to ED and alert on-call onc	ty (ICANs) which can be severe and life-threatening if no	. (
If suspected CRS please initiate work-up utilizing the "C If suspected ICANS please initiate work-utilizing the "IC/		
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If suspected CRS please initiate work-up utilizing the "C If suspected ICANS please initiate work-utilizing the "IC/		
If suspected ICANS please initiate work-utilizing the "IC/ Acknowledge Reason		

- Call center has been educated to send BiTE patients to the ED with any signs and symptoms of CRS/ICANS after hours and alert on-call oncologist
- When ED provider opens the patient's chart, the BPA will fire again stating patient has received BiTE therapy
 - BPA will be active any time therapy plan is placed
- From BPA, ED provider will be guided to initiate the "CRS Initial Work-Up Order Set" (they have been educated on this)

CRS Order Set

• Vitals

▼VITALS

Vital Signs

Vital Signs OBTAIN vitals q1-2 HRS Routine, Q2H, First occurrence today at 1733, OBTAIN vitals q1-2 HRS

• Labs/infectious work-up

Activated Partial Thromboplastin Time

STAT, ONCE TODAY, today at 1733, For 1 occurrence Blood

Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Basic Metabolic Panel

STAT, ONCE TODAY, today at 1733, For 1 occurrence

Blood

Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate Includes BUN, CREATININE, GLUCOSE, NA, K, CL, CALCIUM and TOTAL CO2.

Blood Cultures

Culture, Blood

STAT, ONCE TODAY, today at 1733, For 1 occurrence Blood, peripheral draw Special Requests/Additional Comments: Two separate sites Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Culture, Blood

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C Reactive Protein, Blood

STAT, ONCE TODAY, today at 1733, For 1 occurrence Blood Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate CRP is a general marker for infection and inflamation.

COMPLETE BLOOD CT W/MANUAL DIFF

STAT, ONCE TODAY, today at 1733, For 1 occurrence Blood

BIOOD Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate CRCO - CRC with Manual Differential

Culture, Urine

- STAT, ONCE TODAY, today at 1733, For 1 occurrence
- Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Diagnostics

Order details

Diagnostics EKG-Electrocardiogram STAT, ONCE TODAY, today at 1733, For 1 occurrence X Chest 2 View Routine

D Dimer, Quantitative Routine, ONCE TODAY, today at 1733, For 1 occurrence

Blood

Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

ESR (Sed Rate)

STAT, ONCE TODAY, today at 1733, For 1 occurrence Blood

Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Ferritin

Routine, ONCE TODAY, today at 1733, For 1 occurrence

Blood Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Fibrinogen

STAT, ONCE TODAY, today at 1733, For 1 occurrence

Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

LDH, Serum

STAT, ONCE TODAY, today at 1733, For 1 occurrence

Blood Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Liver Panel

STAT, ONCE TODAY, today at 1733, For 1 occurrence

Blood Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Includes a Total Protein, Albumin, Alkaline Phosphotase, Direct and Total Bilirubin, SGOT and SGPT

Prothrombin Time

STAT, ONCE TODAY, today at 1733, For 1 occurrence Blood

BIOOD Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate

Urinalysis, Auto, Micro if Indicated STAT. ONCE TODAY. today at 1733. For 1 occurrence

 Release to patient. All results release immediately, except the following will release 14 days after being resulted: Surgical and Cytology Specimens, HIVs, Biopsies: Immediate



CRS Order Set



- Easy-access links to CRS and ICANS Grading Tables on ShareWell are in the CRS order Set
 - Links to CRS and ICANs Grading Tables on ShareWell
 - Link to ICE score template
 - Nursing communication how to perform and document ICE score

CRS Grading Table (1)

Routine, UNTIL DISCONTINUED, today at 1759, For 1 occurrence

Link to Document: https://sharewell.thedacare.org/clinical/Cancer%20Business%20Line/MedicalOncology/ layouts/15/WopiFrame2.aspx?sourcedoc=%7B62471181-3030 45A7-98FD-985FA7227A85%7D&file=CRS%20Grading%20Table.docx&action=default&DefaultItemOpen=1

For providers: CRS Grading Table and treatment guidance can be found at the following link.

https://sharewell.thedacare.org/clinical/Cancer%20Business%20Line/MedicalOncology/layouts/15/WopiFrame2.aspx?sourcedoc=%7B62471181-3030-45A7-98FD-9B5FA7227A85%7D&file=CRS%20Grading%20Table.docx&action=default&DefaultItemOpen=1 Please discuss with on-call oncology attending before making any treatment decisions.

ICANS Grading Table

Routine, UNTIL DISCONTINUED, today at 1759, For 1 occurrence

Link to Document: https://sharewell.thedacare.org/clinical/Cancer%20Business%20Line/MedicalOncology/_layouts/15/WopiFrame2.aspx?sourcedoc=%7B5267F6D9-8F76-49D0-B259-B37CE8665325%7D&file=ICANS%20Grading%20Table.docx&action=default&DefaultItemOpen=1

For providers: ICANS Grading Table and treatment guidance can be found at the following link.

https://sharewell.thedacare.org/clinical/Cancer%20Business%20Line/MedicalOncology/_layouts/15/WopiFrame2.aspx?sourcedoc=%7B5267F6D9-8F76-49D0-B259-B37CE8665325%7D&file=ICANS%20Grading%20Table.docx&action=default&DefaultItemOpen=1 Please discuss with on-call oncology attending before making any treatment decisions.

CRS Order Set

- Treatment Medications
 - All by default are unchecked with clear instruction to discuss with oncology provider
 - Medications default with accurate dosing and are capped at 800mg for tocilizumab
 - At this time, tocilizumab is only at our Appleton location, if needed can be sent to our outreach ER or patient will be transferred
 - Tocilizumab is restricted and requires oncology provider approval
 - ➡ MEDICATIONS
 - ▼ TOCILIZUMAB-
 - 🗌 tocilizumab (ACTEMRA) IV

8 mg/kg, Intravenous, once Indications: Cytokine Release Syndrome, Please discuss with patient's primary oncologist or on-call oncology provider before releasing or administering tocilizumab. Tocilizumab can be repeated every 8 hours as needed for a maximum of 3 doses in 24 HRs. A maximum of 4 doses total can be administered.

DEXAMETHASONE

dexAMETHasone (DECADRON) injection

10 mg, Intravenous, once, Please discuss with patient's primary oncologist or on-call oncology provider before releasing or administering dexamethasone.

▼ CEFEPIME (MAXIPIME) IV

NOTE: STAT Once orders are separate to expedite medication administration

ceFEPIme (MAXIPIME) IV

2,000 mg, Intravenous, once, Please start cefepime if neutropenic fever or infection is suspected.

ceFEPIme (MAXIPIME) IV

2,000 mg, Intravenous, every 8 hours, Starting H+8.25 Hours, Please start cefepime if neutropenic fever or infection is suspected.



- ER provider will communicate with on call oncology provider and determine treatment for CRS and or ICANS
- If vitals unstable, patient will be admitted to the ICU
- If vitals are stable, patient will be admitted to the 7th floor for observation
 - If fever free for 48





Instituting BITE Therapy in the Community

PLANNING

(March 2023)

- Order sets
- Learning modules
- BPA
- Beacon plans

EDUCATION

(December 2023)

- In person presentation with each department
- Learning modules completed
- REMS certification

GO LIVE

(March 2024)

- Start of BiTE therapy cycle 2 onwards (step up done at tertiary site)
- After step up process approval, now able to give step up dosing

Special thanks



• Leah Ebben, Dr. Yazhini Vallatharasu and Hematology CoE

