Society for Immunotherapy of Cancer

Cancer Immunotherapy GUIDELINES

Clinical Practice Guideline Webinar –

Immunotherapy for the Treatment of Lymphoma

Monday, January 25, 2021

5 – 6 p.m. EST

Jointly provided by Postgraduate Institute for Medicine and the Society for Immunotherapy of Cancer

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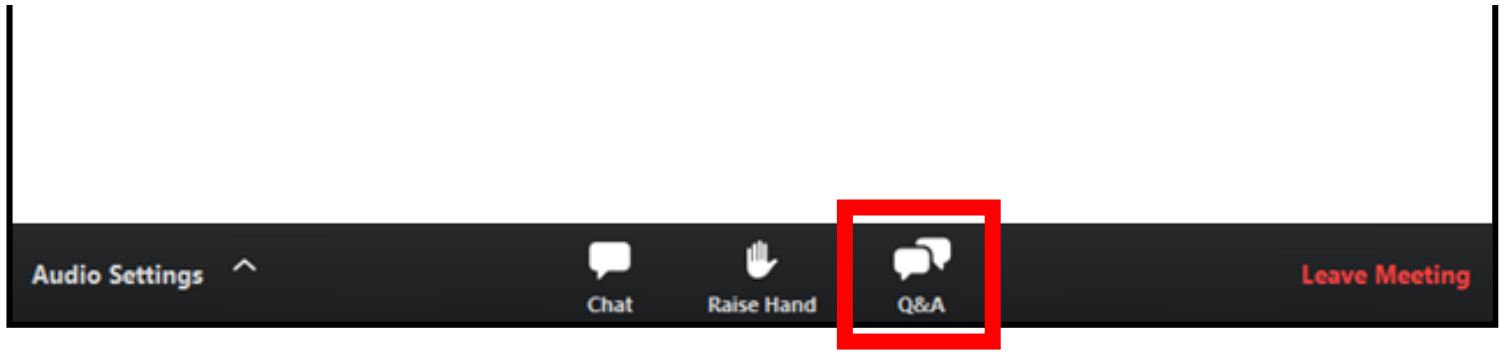
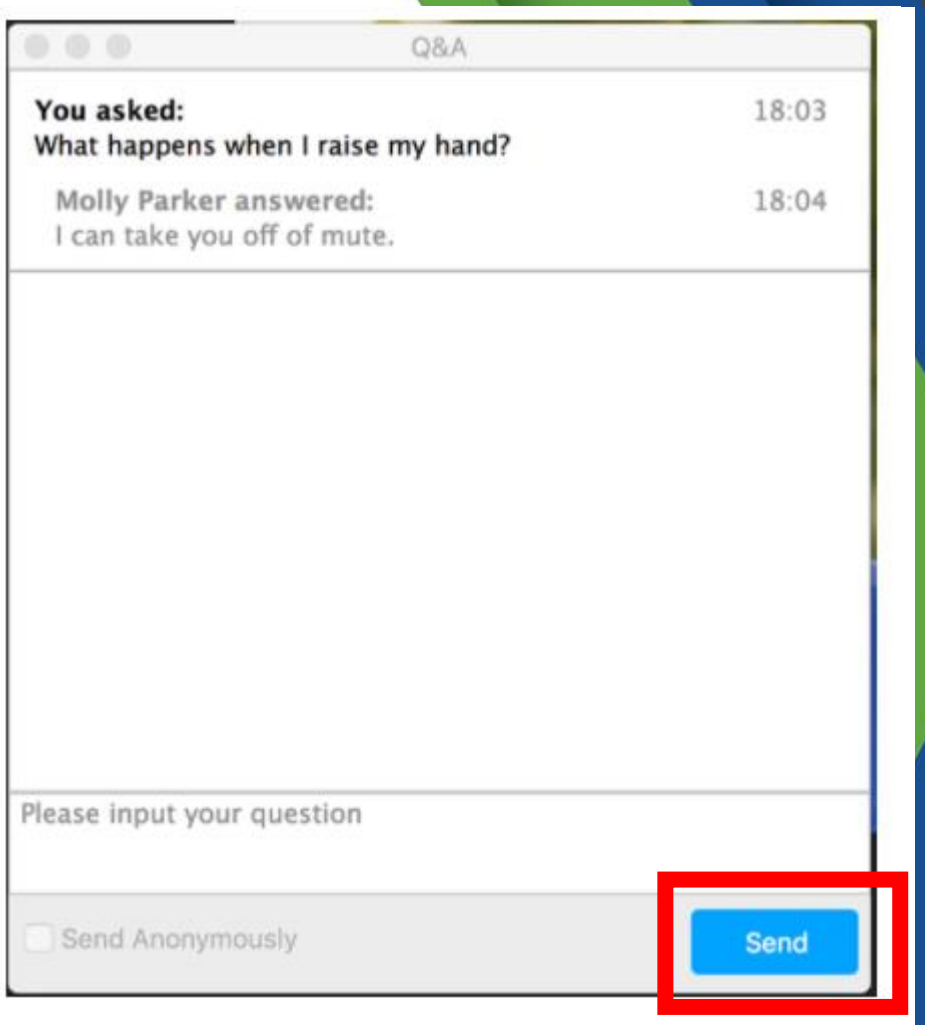
Webinar Agenda

5:00 – 5:05 p.m. ET	Overview: Welcome and Introductions
5:05 – 5:45 p.m. ET	Presentation and discussion of guideline content
5:45 – 5:55 p.m. ET	Question and Answer Session
5:55 – 6:00 p.m. ET	Closing Remarks

How to Submit Questions

- Click the “Q&A” icon located on at the bottom of your Zoom control panel
- Type your question in the Q&A box, then click “Send”
- Questions will be answered in the Question & Answer session at the end of the webinar (as time permits)





Webinar faculty

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MD Anderson Cancer Center

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Outline

- Introduction to lymphoma
- Management of B-cell non-Hodgkin lymphoma
- Management of Hodgkin lymphoma, chronic lymphocytic leukemia and T cell lymphoma
- Toxicity management

Lymphoma

- Most common type of hematologic cancer
- Estimated 85,720 new cases and 20,910 deaths in 2020
- Treatment modalities include chemotherapy, radiotherapy, stem cell transplantation, targeted therapies and immunotherapy

Guideline development

- *The Institute of Medicine's Standards for Developing Trustworthy Practice Guidelines* were used to develop these recommendations
- Panel consisted of 12 participants, including medical oncologists, a pediatric oncologist, a nurse practitioner, and a patient advocate
- Recommendations come from literature evidence, supplemented with clinical experience of the panel members where necessary
- Consensus defined as ≥75% agreement

Guideline development

Position article and guidelines

Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of lymphoma

Sattva S Neelapu[1], Sherry Adkins[1], Stephen M Ansell[2], Joshua Brody[3], Mitchell S Cairo[4], Jonathan W Friedberg[5], Justin P Kline[6], Ronald Levy[7], David L Porter[8], Koen van Besien[9], Michael Werner[10] and Michael R Bishop[6]

Author affiliations +

Abstract

The recent development and clinical implementation of novel immunotherapies for the treatment of Hodgkin and non-Hodgkin lymphoma have improved patient outcomes across subgroups. The rapid introduction of immunotherapeutic agents into the clinic, however, has presented significant questions regarding optimal treatment scheduling around existing chemotherapy/radiation options, as well as a need for improved understanding of how to properly manage patients and recognize toxicities. To address these challenges, the Society for Immunotherapy of Cancer (SITC) convened a panel of experts in lymphoma to develop a clinical practice guideline for the education of healthcare professionals on various aspects of immunotherapeutic treatment. The panel discussed subjects including treatment scheduling, immune-related adverse events (irAEs), and the integration of immunotherapy and stem cell transplant to form recommendations to guide healthcare professionals treating patients with lymphoma.

General recommendations for lymphoma

- **Clinical trials** should be strongly considered as a treatment option at each stage of therapy for eligible patients with lymphoma.
- All patients newly diagnosed with lymphoma should receive initial imaging via **FDG-PET/CT**.
- Patients should be routinely administered **complete blood count (CBC) and serum IgG tests**. Infection precautions may be considered in patients with decreased neutrophil and absolute lymphocyte counts from CBC tests, as well as low levels of serum IgG.
- All patients with newly diagnosed lymphoma should receive assessment of their **cardiovascular history** and risk factors prior to receiving potentially cardiotoxic therapies.

Outline

- Introduction to lymphoma
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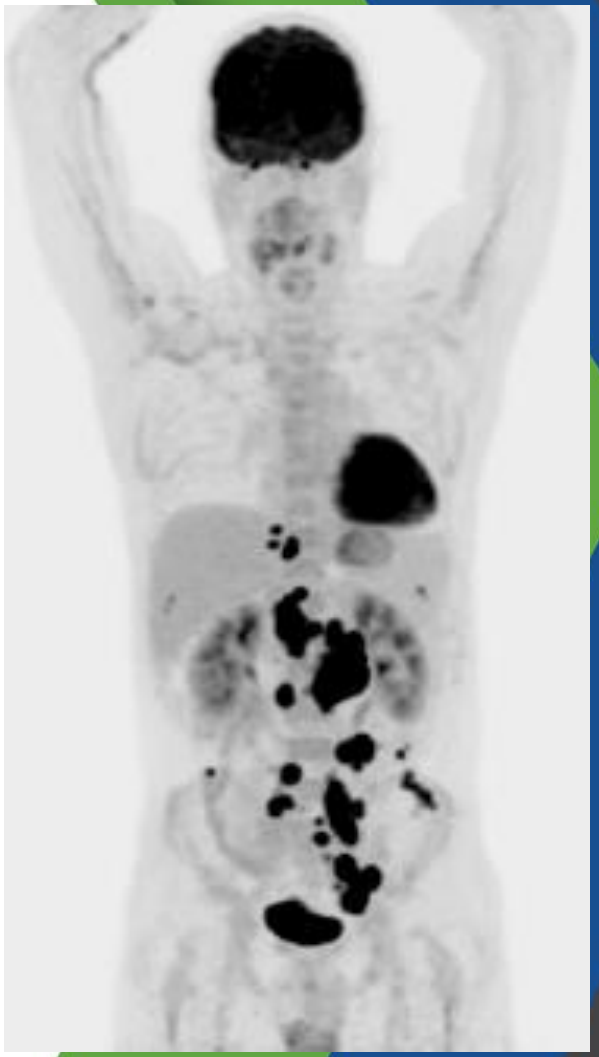
- Management of Hodgkin lymphoma, chronic lymphocytic leukemia and T cell lymphoma
- Toxicity management

Diffuse Large B-cell Lymphoma Case

- 47 yo male who presented with stage IVB DLBCL with bulky retroperitoneal lymphadenopathy of up to 15 cm in size
- Had partial response after 4 cycles of DA-EPOCH-R but progressed after cycle 6
- After 1 cycle of R-DHAP he had increasing back pain and a CT scan revealed progressive disease
- Treatment options approved for 2nd or 3rd line DLBCL:
  - CAR T-cell therapy
  - Polatuzumab + bendamustine + rituximab
  - Tafasitamab + lenalidomide
- What is the best treatment option for this patient?



Treatment of NHL

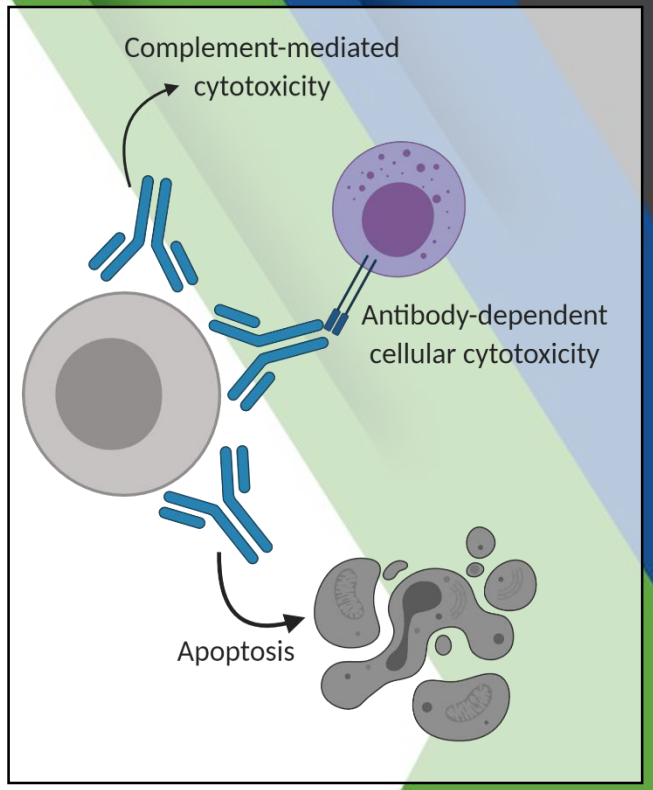
Immunotherapy options include:

- Monoclonal antibodies
  - Rituximab
  - Obinutuzumab
  - Mogamulizumab-kpkc
  - Tafasitamab-cxix
- Antibody-drug conjugates
  - Ibritumomab tiuxetan
  - Brentuximab vedotin
  - Polatuzumab vedotin-piiq
- Cellular therapies
  - Axicabtagene ciloleucel
  - Tisagenlecleucel
  - Brexucabtagene autoleucel
- Immunomodulators
  - Lenalidomide
- Immune checkpoint inhibitors
  - Pembrolizumab

Rituximab

Anti-CD20 antibody

- Approved for:
  - R/R low grade or follicular CD20-positive B-cell NHL as a single agent
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first-line chemotherapy and, in patients achieving a CR or PR to rituximab + chemotherapy, as single-agent maintenance
  - Non-progressing low-grade CD20-positive B-cell NHL as single agent after first-line cyclophosphamide, vincristine and prednisone
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline chemotherapy



Obinutuzumab

Anti-CD20 antibody

- Approved for:
  - R/R follicular lymphoma after rituximab, in combination with bendamustine, followed by obinutuzumab monotherapy
  - Previously untreated stage II bulky, III or IV follicular lymphoma, in combination with chemotherapy, followed by obinutuzumab monotherapy if achieving at least a PR

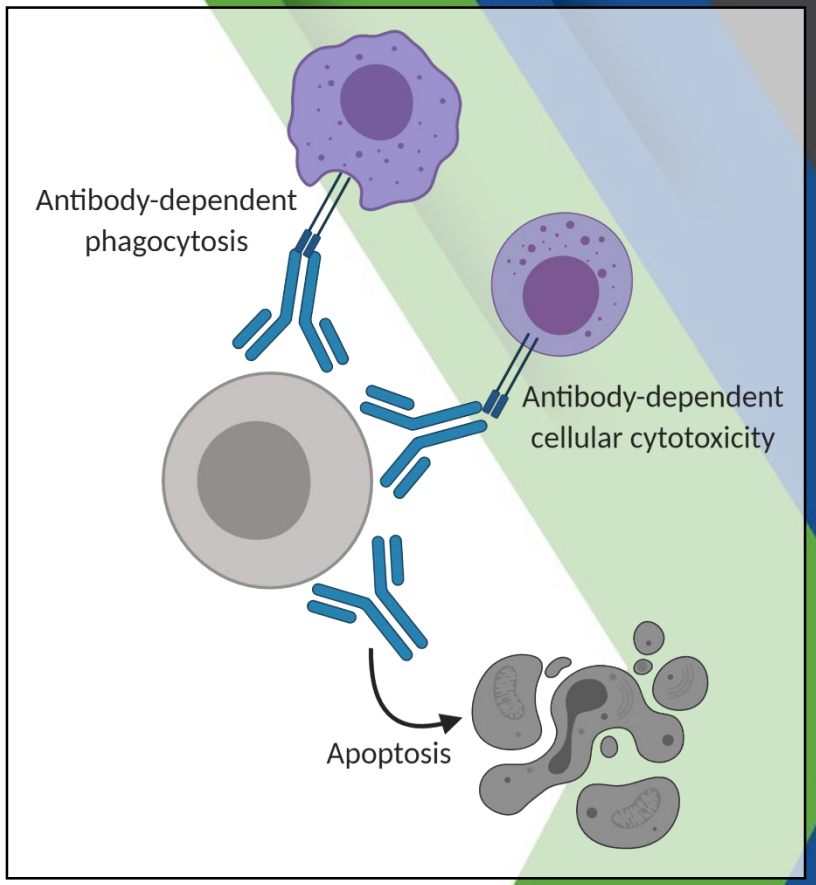
Rituximab	Obinutuzumab
Type I antibody	Type II antibody
Localization of CD20 into lipid rafts	No localization of CD20 into lipid rafts
Minimal direct cell death (DCD)	More potent direct cell death (DCD)
Prominent complement-dependent cytotoxicity (CDC)	Minimal complement-dependent cytotoxicity (CDC)
Some antibody-dependent cellular cytotoxicity	More potent antibody-dependent cellular cytotoxicity
Some antibody-dependent phagocytosis	More potent antibody-dependent phagocytosis

Freeman, Br J Hematol 2018

Tafasitamab-cxix

Anti-CD19 antibody

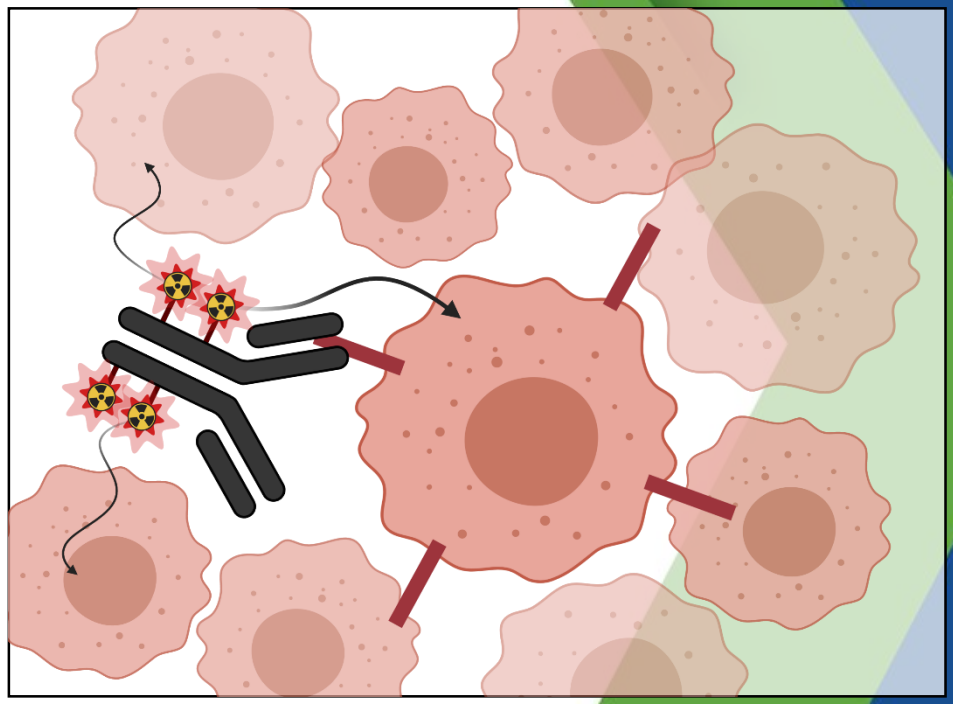
- Approved for: R/R DLBCL in combination with lenalidomide for patients ineligible for autoSCT
- Fc engineering enhances ADCC and ADP compared to unmodified IgG
- Panel noted tafasitamab + lenalidomide as a treatment option for second-line treatment of transplant-ineligible DLBCL



Ibritumomab tiuxetan

Anti-CD20 antibody + ^{90}Y

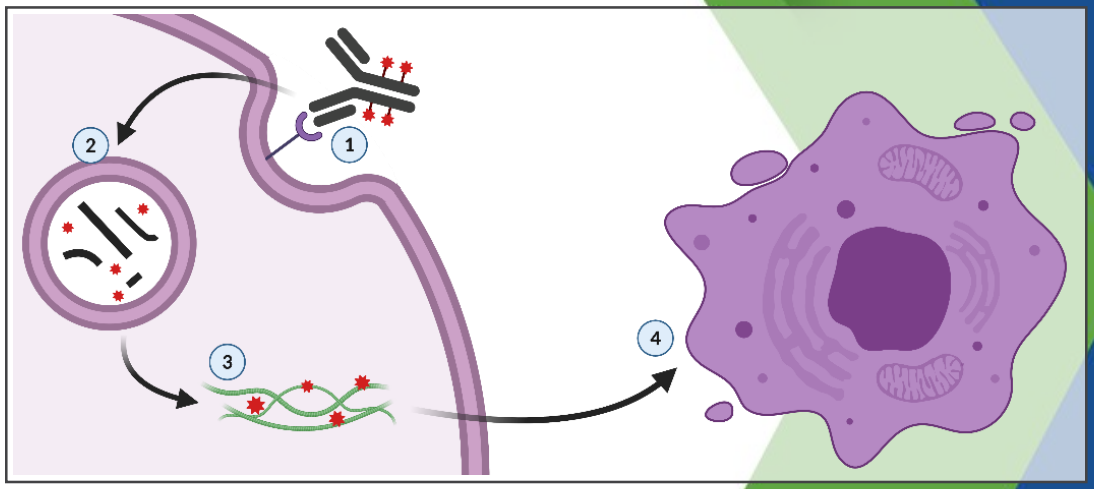
- Delivers cytotoxic radiation to CD20-expressing cells
- Approved for:
  - R/R low-grade or follicular NHL
  - Follicular NHL with a PR or CR to first-line chemotherapy
- Requires additional handling/safety considerations, since radioactive
- Dosing in units of millicurie (mCi) per kg



Polatuzumab vedotin-piiq

Anti-CD79b antibody + monomethyl auristatin E

- Approved for:
  - R/R DLBCL after at least two prior therapies, in combination with rituximab and bendamustine
- Committee recommends PV as the third-line treatment for patients with DLBCL who are ineligible for CAR T therapy.

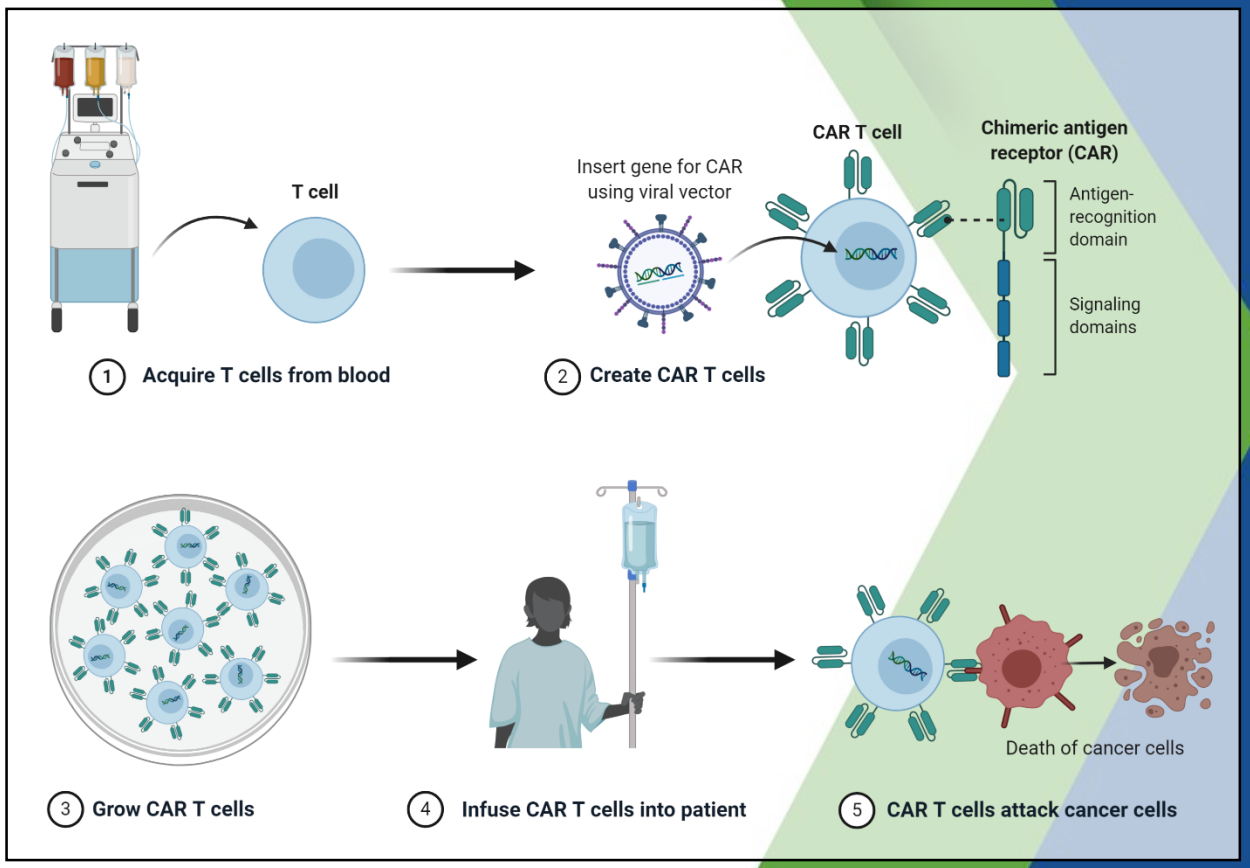


Axicabtagene ciloleucel, tisagenlecleucel and brexucabtagene autoleucel

CD19 CAR T therapies

Agent	Approved indication
Axicabtagene ciloleucel	R/R large B cell lymphomas after 2+ prior therapies
Tisagenlecleucel	R/R large B cell lymphomas after 2+ prior therapies
Brexucabtagene autoleucel	R/R MCL

Axi-cel and brexu-cel have the same CAR construct; however, the manufacturing of brexu-cel involves enrichment of specific lymphocytes to improve therapeutic potential.



Recommendations for DLBCL

First-line treatment	Second-line treatment	Third-line treatment (or later)
• Adults: R-CHOP • Pediatric: **rituximab** + FAB chemotherapy	• Transplant eligible: chemoimmunotherapy regimen that includes **rituximab**, followed by autoSCT if CR achieved • *Transplant-ineligible: no consensus. Options: lenalidomide, lenalidomide + **tafasitamab**, polatuzumab vedotin + BR, or salvage chemoimmunotherapy*	• **Anti-CD19 CAR T therapy** • CAR-ineligible: polatuzumab vedotin + rituximab + bendamustine

DLBCL Case Study

- The **first-line regimen** for newly diagnosed DLBCL in adult patients should be R-CHOP or R-CHOP-like regimens.
- For the **second-line therapy** of DLBCL, transplant-eligible patients should receive a chemoimmunotherapy regimen that includes rituximab followed by autoSCT consolidation if CR is achieved.
- The **third-line treatment** for DLBCL in fit patients should be anti-CD19 CAR T cell therapy.
  - Anti-CD19 CAR T-cell therapy should be considered prior to tafasitamab + lenalidomide therapy in CART-eligible patients
- Patients who are **ineligible for third-line anti-CD19 CAR T** cell therapy should instead receive polatuzumab vedotin-piiq+ rituximab+bendamustine.
  - Bendamustine should be avoided prior to apheresis in CART-eligible patients

Recommendations for MCL

First-line treatment	Second-line treatment	Third-line treatment (or later)
• *Transplant-eligible: No consensus* • *Options: chemoimmunotherapy + autoSCT or chemoimmunotherapy alone* • Transplant-ineligible: chemoimmunotherapy + **rituximab maintenance**	• *No consensus* • *Options:* ***brexucabtagene autoleucel,*** *proteasome inhibitors, BTK inhibitors, BTK inhibitors + rituximab, or lenalidomide +* ***rituximab***	• *No consensus*

Recommendations for FL

First-line treatment

- *Low tumor burden: no consensus*
- *Options include:* ***rituximab****,* ***lenalidomide + rituximab****, or chemoimmunotherapy*
- High tumor burden: chemoimmunotherapy

Second-line treatment

- Options will vary and should be decided on case-by-case basis, factoring in:
  - Prior therapies
  - Time of relapse
  - Tumor bulk
  - Age
  - Comorbidities

Third-line treatment (or later)

Notes:

- When anti-CD20 antibody is indicated, rituximab should be used over obinutuzumab
- If relapse occurs <6 months after rituximab, obinutuzumab should be used
- If relapse occurs >6 months after rituximab, re-administration of rituximab can occur

Recommendations for MZL

First-line treatment

- Low tumor burden: **rituximab** monotherapy
- High tumor burden: chemoimmunotherapy

Second-line treatment

- Options will vary and should be decided on case-by-case basis, factoring in:
  - Prior therapies
  - Time of relapse
  - Tumor bulk
  - Age
  - Comorbidities

Third-line treatment (or later)

Recommendations for PMBCL

First-line treatment	Second-line treatment	Third-line treatment (or later)
• DA-R-EPOCH	• Transplant eligible: chemoimmunotherapy regimen that includes **rituximab**, followed by autoSCT if CR achieved. • *Transplant-ineligible: no consensus. Options: lenalidomide, lenalidomide + **tafasitamab**, **polatuzumab vedotin** + BR, or salvage chemoimmunotherapy*.	• *No consensus.* • *Options: **axicabtagene ciloleucel**, **BV + pembrolizumab**, salvage chemoimmunotherapy.*

Recommendations for BL - pediatric

First-line treatment	Second-line treatment	Third-line treatment (or later)
• **Rituximab-containing** chemoimmunotherapy, with either FAB or BFM backbone	• **Rituximab-containing** chemoimmunotherapy • Options: R-ICE or R-CYVE	• Patients should receive stem cell transplant if eligible.

Recommendations for BL - adult

First-line treatment

- **Rituximab-containing** chemoimmunotherapy.
- Options: rituximab + CODOXM/IVAC alternating with rituximab + HyperCVAD, rituximab + LMB

Second-line treatment

- Similar **rituximab-containing** chemoimmunotherapy
- Consolidation similar to DLBCL

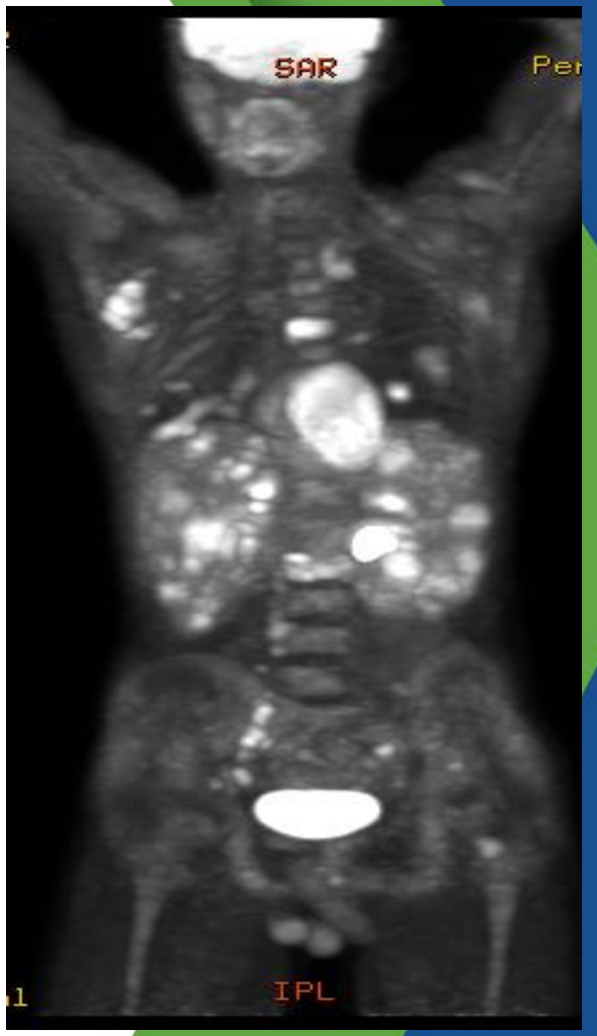
Third-line treatment (or later)

Outline

- Introduction to lymphoma
- Management of B-cell non-Hodgkin lymphoma
- Management of Hodgkin lymphoma, chronic lymphocytic leukemia and T cell lymphoma
- Toxicity management

Hodgkin lymphoma case

- A 27 year old male presents with stage IVA nodular sclerosis Hodgkin lymphoma.
- He has diffuse lymphadenopathy; liver, lung and splenic lesions and multiple bone lesions on PET scan.
- He receives brentiximab vedotin + AVD x 6 cycles and has a CR
- He has a biopsy proven relapse 9 months later
- He receives ICE chemotherapy followed by an autologous stem cell transplant and brentuximab vedotin for 1 year
- The patient relapses again 6 months after completing 16 cycles of brentuximab vedotin and is treated with nivolumab.
- He has a CR and is offered an allogenic transplant, but declines.
- He remains in remission 4 years later

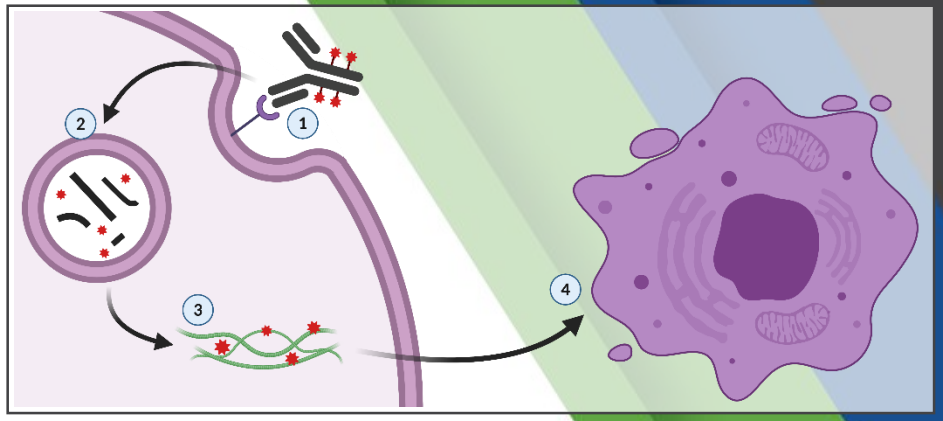


Approved immunotherapies for Hodgkin lymphoma

Agent	Therapy type	Indication(s)
Brentuximab vedotin	ADC	First-line stage III-IV cHL (combination with doxorubicin, vinblastine and dacarbazine)
		Consolidation therapy for cHL after autoSCT and high risk of relapse
		R/R cHL after autoSCT
Nivolumab	ICI	R/R cHL after autoSCT and brentuximab vedotin
		R/R cHL after 3+ prior therapies
Pembrolizumab	ICI	R/R cHL after 3+ prior therapies

Brentuximab vedotin

Anti-CD30 antibody + monomethyl auristatin E



Trial	Study design	Patient population	Enrolled patients	Primary endpoint	Results
ECHELON-1	Randomized phase III; comparator: ABVD	First line stage III or IV cHL	1334	Modified PFS	2-yr PFS: 82.1 vs 77.2% 2-yr OS: 96.6 vs 94.9%
AETHERA	Randomized phase III; comparator: BSC	cHL at high risk of relapse after autoSCT	329	PFS	5-yr PFS: 59 vs 41%
NCT00848926	Phase II, single-arm	R/R cHL with prior autoSCT	102	ORR	ORR: 75% CR rate: 34%

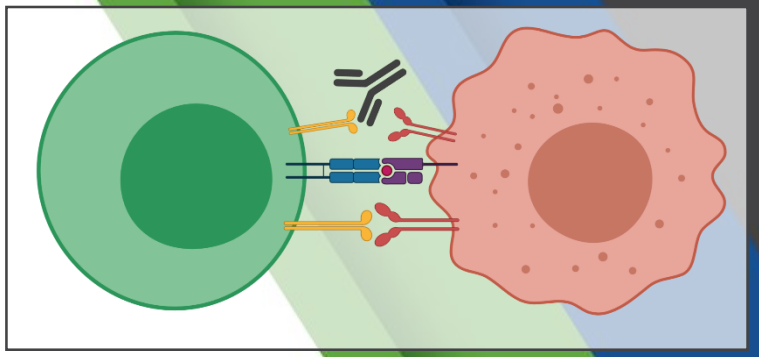
Recommended uses in HL:

- Pre-autoSCT with chemotherapy, ICI, or monotherapy
- First-line stage III-IV with AVD
- Third-line treatment

Connors, N Engl J Med 2018.
Moskowitz, Blood 2018.
Younes, J Clin Oncol 2012.

Nivolumab and pembrolizumab

Anti-PD-1 antibodies



Trial	Study design	Patient population	Enrolled patients	Primary endpoint	Results
CheckMate 205	Phase II single-arm, nivolumab	R/R cHL with prior autoSCT +/- BV	243	ORR	ORR: 69% Median PFS: 14.7 mo
NCT02572167	Phase I/II single-arm, nivolumab + BV	R/R cHL second-line	62	CR rate	CR rate: 61% ORR: 83%
KEYNOTE-087	Phase II single-arm, pembrolizumab	R/R cHL	210	ORR and safety	ORR: 69% 6-month PFS: 72.4%

Recommended uses in HL:

- Pre-autoSCT with BV
- Third-line treatment

Armand, J Clin Oncol 2018.
Herrera, Blood 2018.
Chen, J Clin Oncol 2017.

Recommendations for HL

First-line treatment	Second-line treatment	Third-line treatment (or later)

• Stage I-II: doxorubicin, bleomycin, vinblastine and dacarbazine (ABVD)
• *Stage III-IV: no consensus. Options:*
  • *ABVD*
  • ***Brentuximab vedotin**, doxorubicin, vinblastine and dacarbazine (A-AVD*
	• Salvage chemotherapy or immunotherapy, and autoSCT if eligible. Pre-autoSCT options include:
	  • **Brentuximab vedotin + bendamustine**
	  • Ifosfamide + carboplatin + etoposide
	  • **Brentuximab vedotin + nivolumab**
	  • **Brentuximab vedotin monotherapy**
		• *No consensus. Options:*
		  • *Salvage chemotherapy or immunotherapy + autoSCT if eligible*
		  • ***PD-1 inhibitor therapy***
		  • ***Brentuximab vedotin***

Hodgkin lymphoma case

1. Brentuximab vedotin is standardly included in initial chemotherapy combinations
2. Brentuximab vedotin should be given as consolidation therapy after autologous stem cell transplantation in high-risk patients
3. Anti-PD1 antibodies are standard of care in relapsed Hodgkin lymphoma patients post autologous transplant
4. Consider allogeneic transplant or a clinical trial if the disease progresses

Recommendations for PTCL

First-line treatment

- *CD30+: no consensus*
- *Options: **BV + CHP**, chemotherapy, chemotherapy + autoSCT*
- CD30-negative: chemotherapy + autoSCT

Second-line treatment

- *Eligible for transplant: no consensus.*
- *Options: chemotherapy + autoSCT, chemotherapy + alloSCT, HDAC inhibitors*
- CD30+, SCT-ineligible: **BV up to 16 doses**
- CD30-, SCT-ineligible: HDAC inhibitors

Third-line treatment (or later)

Approved therapies for CLL

Agent	Treatment type	Indication(s)
Rituximab	Anti-CD20 antibody	**Untreated** CD20-positive CLL in combination with FC
		R/R CD20-positive CLL in combination with FC
Obinutuzumab	Anti-CD20 antibody	**Untreated** CLL in combination with chlorambucil
Ofatumumab	Anti-CD20 antibody	**Untreated**, fludarabine-ineligible CLL in combination with chlorambucil
		Relapsed CLL in combination with FC
		Extended treatment of CLL in CR or PR after 2+ prior therapies
		CLL **refractory** to fludarabine and alemtuzumab
Alemtuzumab	Anti-CD52 antibody	**Untreated** or R/R CLL

The panel did not reach consensus on preferred regimens for the first-line or second-line treatment of CLL. Options include targeted therapy (if eligible) and chemoimmunotherapy regimens, which may include rituximab, obinutuzumab, ofatumumab, and alemtuzumab.

Outline

- Introduction to lymphoma
- Management of B-cell non-Hodgkin lymphoma
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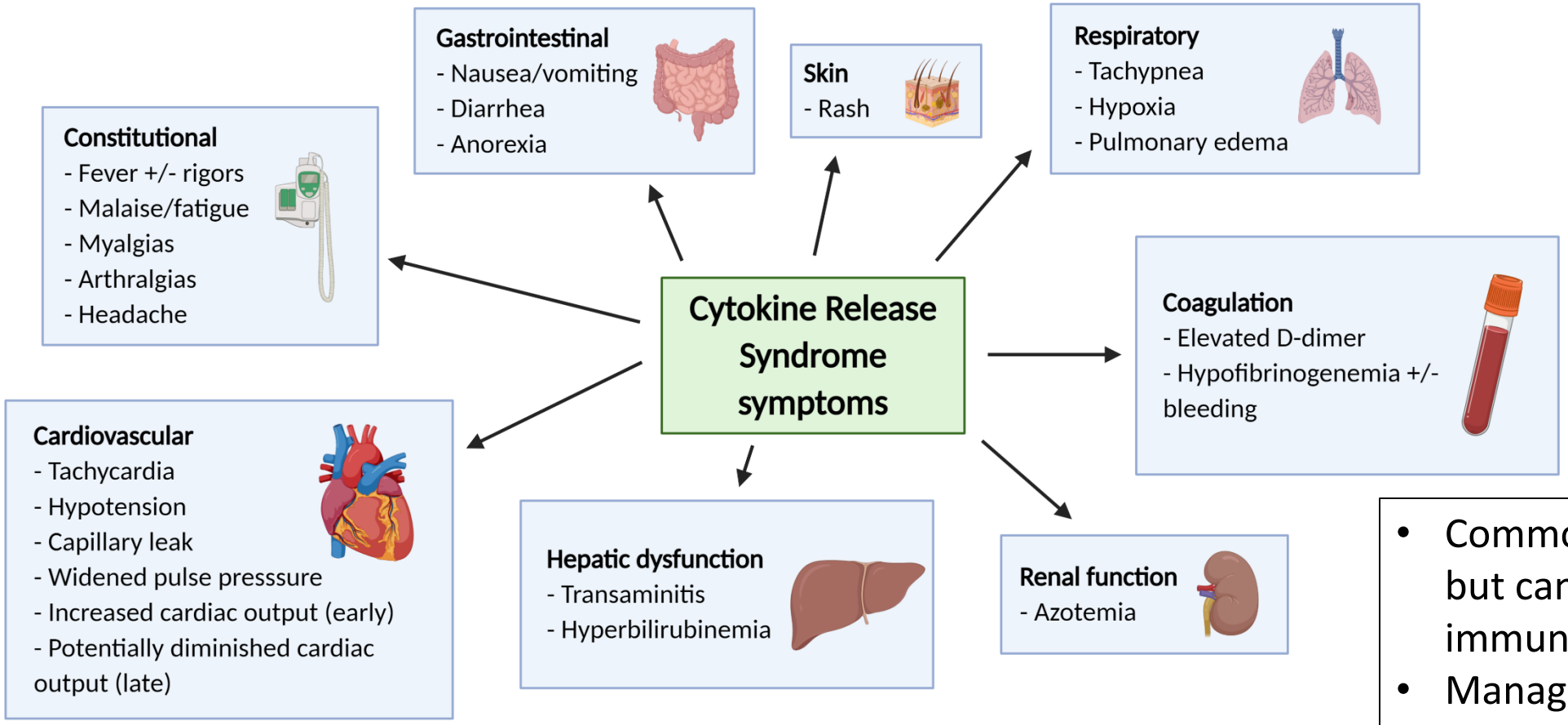
“Black box” warnings on lymphoma immunotherapies

Therapy	Warning due to
Alemtuzumab	• Autoimmune conditions • Severe infusion reactions • Anaphylaxis • Cancer • Infections
Axicabtagene ciloleucel	• CRS • ICANS • Do not administer if active infection or inflammation
Brexucabtagene autoleucel	• CRS • ICANS • Do not administer if active infection or inflammation
Brentuximab vedotin	• PML
Obinutuzumab	• Hepatitis B reactivation • PML
Ibritumomab tiuxetan	• Severe infusion reactions • Severe cytopenia • Severe cutaneous/mucocutaneous reactions • Do not administer if altered biodistribution
Lenalidomide	• Embryo-fetal toxicity • Significant neutropenia, thrombocytopenia
Rituximab and biosimilars	• Severe infusion reactions • TLS • Severe mucocutaneous reactions • PML • Hepatitis B reactivation
Tisagenlecleucel	• CRS • ICANS • Do not administer if active infection or inflammation

Cytokine release syndrome



- Common with CAR T therapy but can occur with other immunotherapies.
- Management includes tocilizumab and corticosteroids.

Neurotoxicity

- Also called CAR-T Related Encephalopathy Syndrome (CRES) or IEC-associated neurologic syndrome (ICANS)
- Manifests as confusion, delirium, seizures, cerebral edema
- Largely unknown mechanisms
- Incidence increases with more doses, increased age, more prior therapies
- Management options:
  - Supportive care
  - Corticosteroids

Neurotoxicity Domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE score	7-9	3-6	0-2	0
Depressed level of consciousness	Awakens spontaneously	Awakens to voice	Awakens to tactile stimulus	Unrousable
Seizure	N/A	N/A	Any clinical seizure/on EEG	Prolonged/life-threatening seizure
Motor Findings	N/A	N/A	N/A	Hemi or paraparesis, deep focal motor weakness
Raised ICP/ cerebral edema	N/A	N/A	Focal edema on imaging	Diffuse cerebral edema on imaging, cranial N palsy, Cushing's triad, Decorticate posture

Wang Z. Biomark Res. 2018; Hunter BD. J Natl Cancer Inst. 2019

Infusion reactions

- Can be allergic or non-allergic
- Allergic reactions uncommon, but can lead to anaphylaxis
- Infusion reactions are common, particularly when mAbs are administered after SCT
- Most infusion reactions occur with first dose of therapy
- Among lymphoma immunotherapies, rituximab has highest incidence of infusion reactions, up to 77%

Tumor lysis syndrome

- Result of a sudden and massive release of metabolites after widespread lysis of tumor cells
- Particularly high risk in hematologic cancers with high tumor burden
- Management approaches include:
  - Prophylactic hydration
  - Prophylactic hypouricemic agents, like allopurinol
  - Dialysis

Patients with viral infections

- Reactivation of hepatitis B infection has been reported after certain antibody therapies, including rituximab and BV
- Panel recommends **not treating patients with active viral infections** with CAR T therapy or alloSCT
- Patients should be **evaluated for HBV/HCV** prior to immunotherapy, and antivirals should be initiated if positive
- Patients with **HIV can be considered** for immunotherapy if their HIV is well-controlled

Conclusions

- **Clinical trials** should be strongly considered as a treatment option at each stage of therapy for eligible patients with lymphoma.
- The immunotherapy options for B-NHL are broad include rituximab as a standard for newly diagnose disease. CAR T cells have emerged as the preferred option for relapsed/refractory disease while polatuzumab vedotin is available for CAR-ineligible patients.
- Brentuximab vedotin has been incorporated into both frontline and second-line therapies for HL. Checkpoint inhibitors are standard options in the relapsed/refractory settings
- Careful consideration, monitoring and management are necessary when immunotherapies are utilized in lymphoma.

How to Submit Questions

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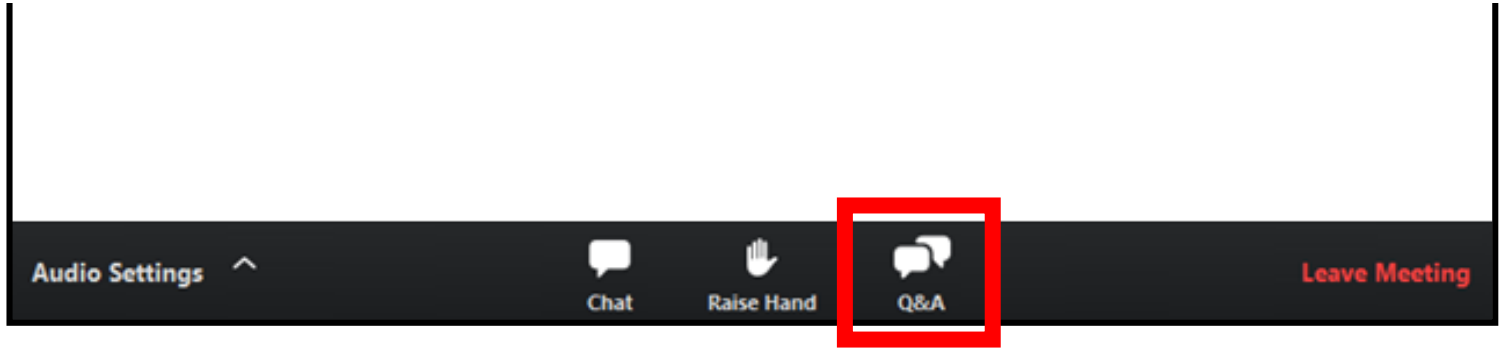

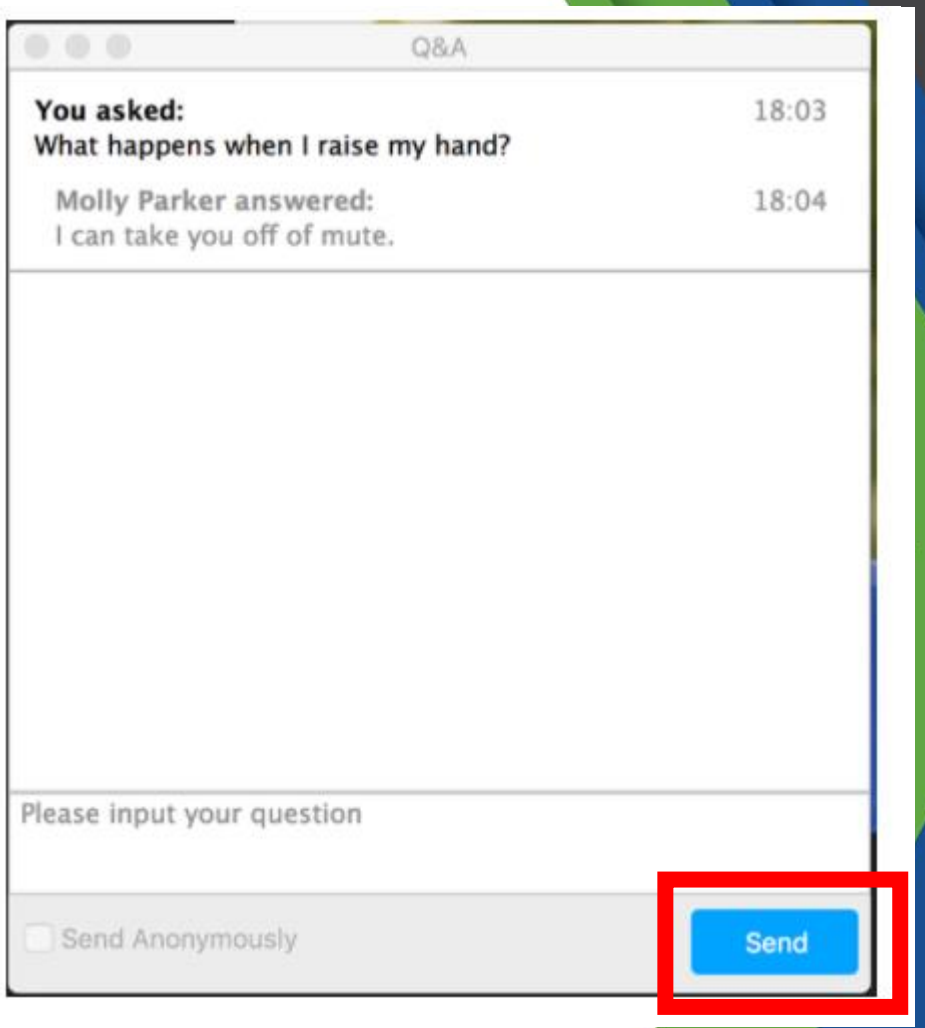

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Clinical Practice Guideline Webinar – Immune Effector Cell-related Adverse Events

Friday, March 5 at 3 – 4 p.m. ET

Faculty:

Stephan Grupp, MD, PhD – *Children's Hospital of Philadelphia and U. of Pennsylvania*
Matthew J. Frigault, MD, MSc – *Massachusetts General Hospital*
Frederick L. Locke, MD – *Moffitt Cancer Center*
Bianca D. Santomasso, MD, PhD – *Memorial Sloan Kettering Cancer Center*

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