Society for Immunotherapy of Cancer

Cancer Immunotherapy GUIDELINES

Immune Checkpoint Inhibitor-related Adverse Events

August 13, 2021

10 - 11 a.m. ET

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

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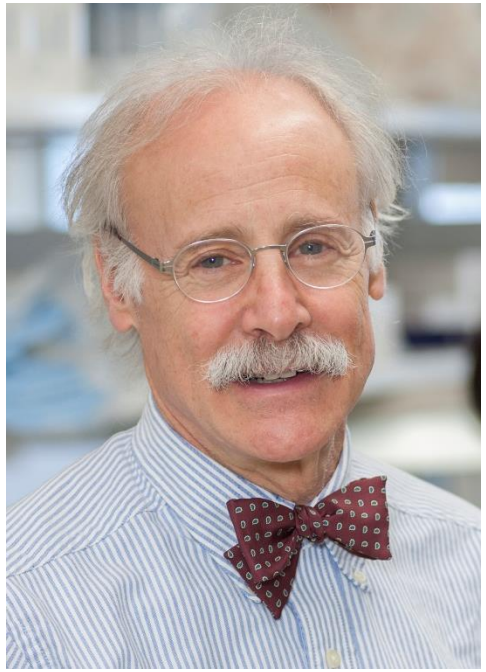
Webinar Agenda

10:00 – 10:05 a.m. ET	Overview: Welcome and Introductions
10:05 – 10:40 a.m. ET	Presentation and Discussion
10:40 – 10:55 a.m. ET	Question and Answer Session
10:55 – 11:00 a.m. ET	Closing Remarks

Moderators

Julie R. Brahmer, MD, MSc –
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins



Marc S. Ernstoff, MD –
National Institutes of Health

Presenters

Gregory A. Masters, MD, FACP, FASCO – *Helen F. Graham Cancer Center*

Paolo A. Ascierto, MD – *Instituto Nazionale Tumori IRCCS, Fondazione 'G. Pascale'*

Igor Puzanov, MD, MSCI, FACP – *Roswell Park Comprehensive Cancer Center*

Learning objectives

1. Select appropriate diagnostics and biomarker testing for a patient being considered for immunotherapy based on the expert panel recommendations in the SITC Clinical Practice Guideline (CPG)
2. Implement immunotherapy treatments effectively and appropriately according to the recommendations in the CPG
3. Appraise patterns of response to immunotherapy in order to appropriately monitor and manage patients during treatment
4. Identify signs and symptoms of common immunotherapy-related toxicities and implement appropriate management strategies based on the Expert Panel recommendations
5. Describe considerations and available tools to assess and support patient quality of life during immunotherapy treatment

Open access Position article and guidelines

Journal for ImmunoTherapy of Cancer

Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immune checkpoint inhibitor-related adverse events

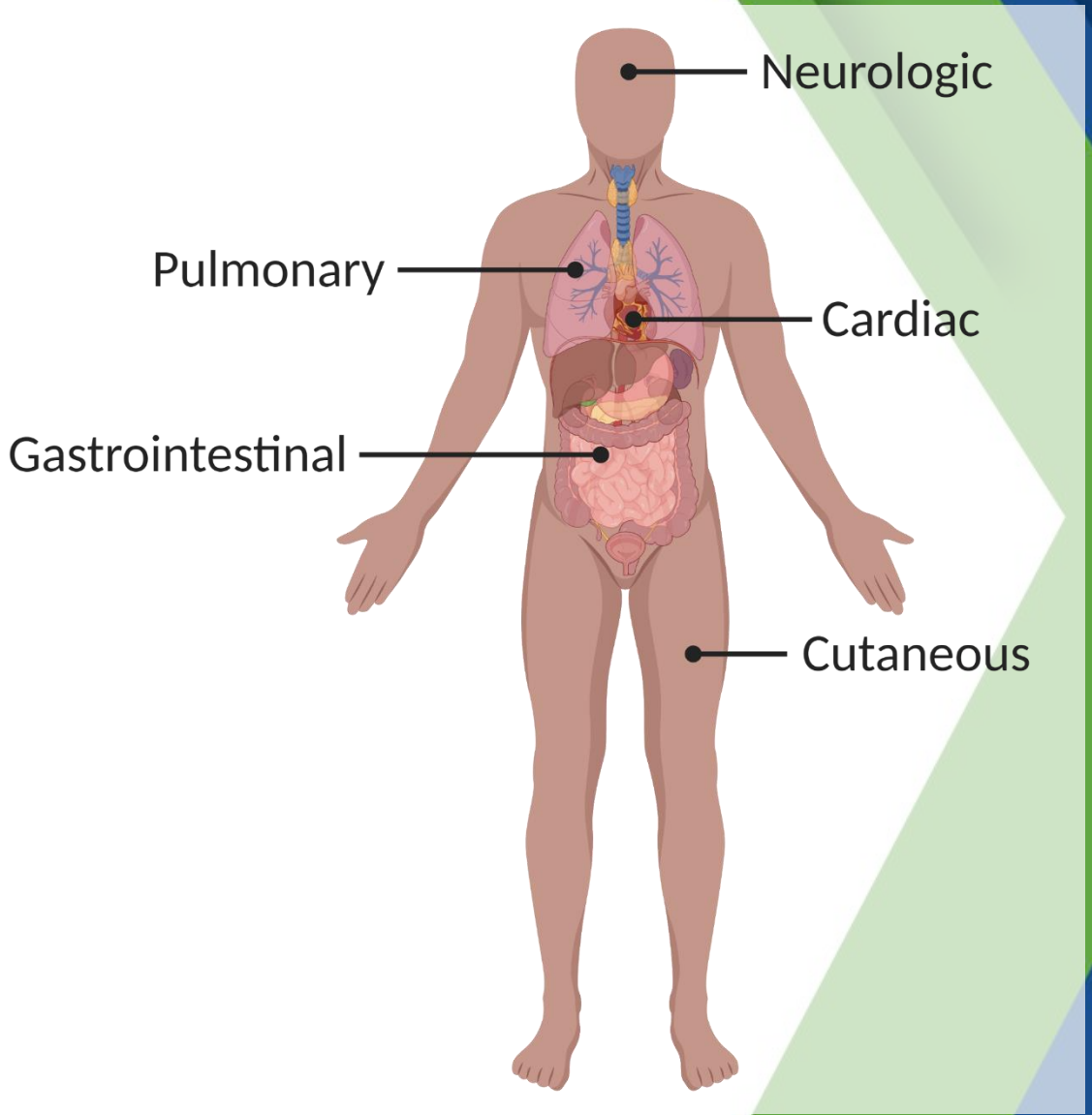
Julie R Brahmer,[1] Hamzah Abu-Sbeih,[2] Paolo Antonio Ascierto ,[3] Jill Brufsky,[4] Laura C Cappelli,[5] Frank B Cortazar,[6,7] David E Gerber,[8] Lamya Hamad,[9] Eric Hansen,[10] Douglas B Johnson,[11] Mario E Lacouture,[12] Gregory A Masters,[13] Jarushka Naidoo,[1,14] Michele Nanni,[10] Miguel-Angel Perales,[12] Igor Puzanov,[10] Bianca D Santomasso,[15] Satish P Shanbhag,[5,16] Rajeev Sharma,[10] Dimitra Skondra,[17] Jeffrey A Sosman,[18] Michelle Turner,[1] Marc S Ernstoff [19]

Guideline development

- Developed according to the Institute of Medicine's Standards for Developing Trustworthy Clinical Practice Guidelines
- Panel consisted of 23 experts in the field
- Recommendations are based upon published literature evidence, or clinical evidence where appropriate
- Consensus was defined at 75% approval among voting members

Webinar outline

- Introduction to the Guideline
- General irAE management
- Managing common irAEs
  - Gastrointestinal
  - Cutaneous
- Managing serious irAEs
  - Cardiac
  - Pulmonary
  - Neurologic
- Other life-threatening toxicities



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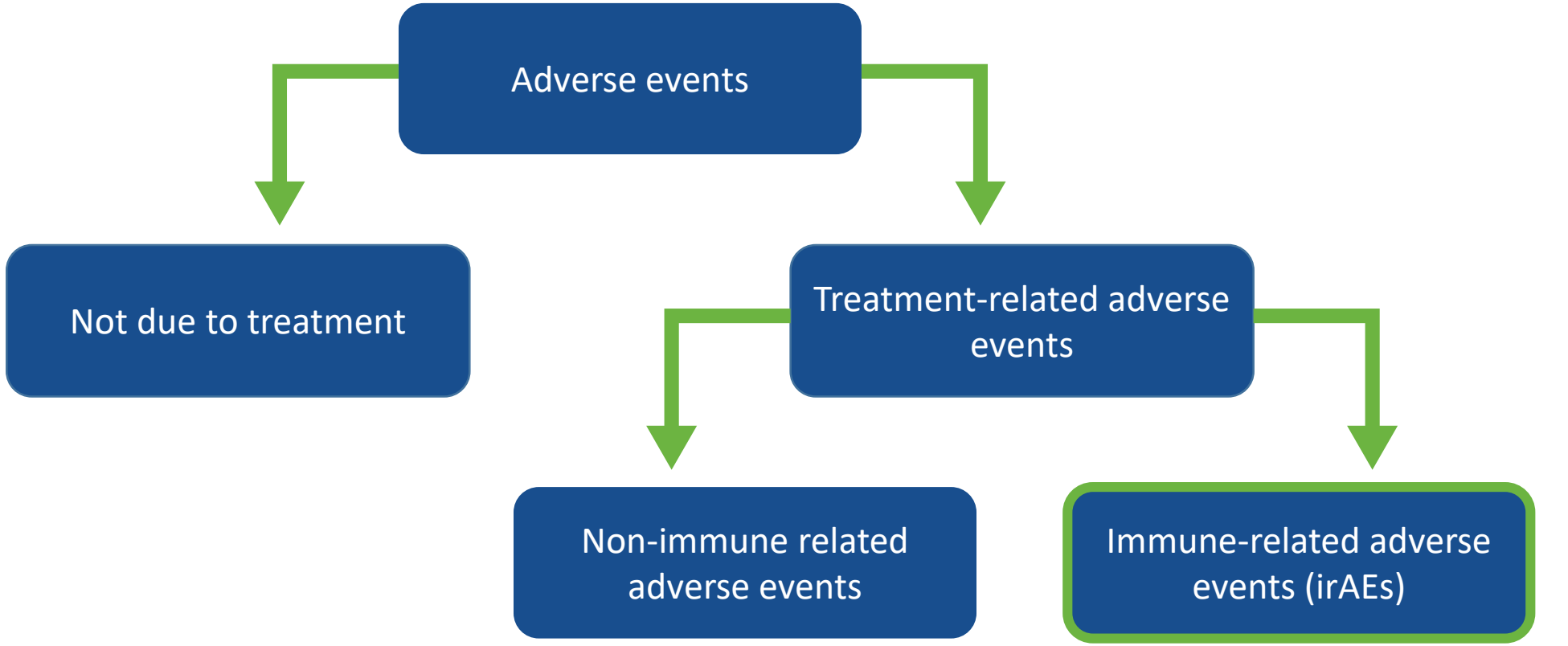
Types of adverse events



- Can result from all ICIs
- Can impact any organ system

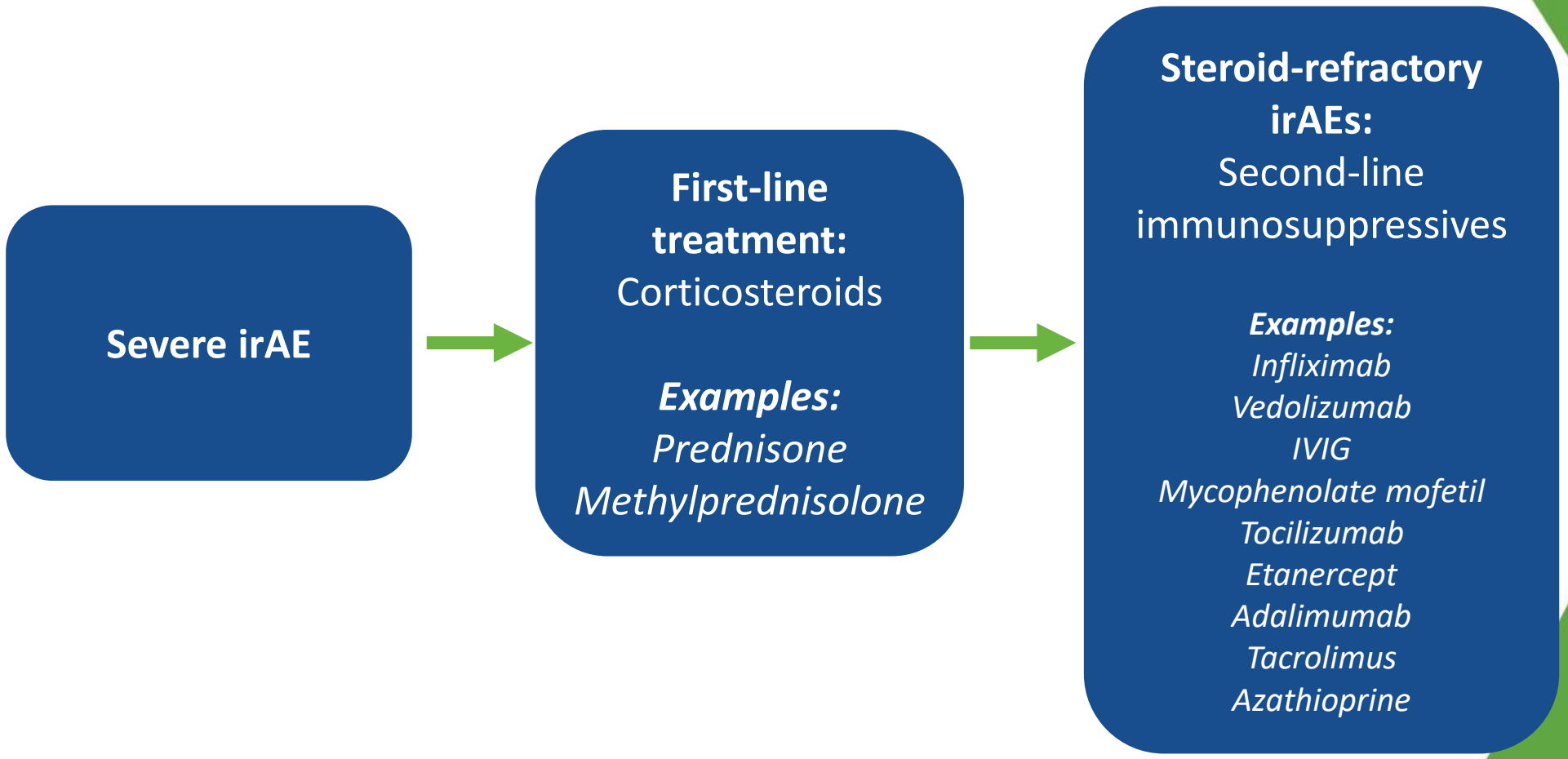
Common terminology criteria for adverse events (CTCAE)

CTCAE grade	Clinical description
1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2	Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL
4	Life-threatening consequences; urgent intervention indicated
5	Death related to adverse event

Throughout the Guidelines, CTCAE v5.0 is used for definitions and grading of AEs.
ADL: Activities of daily living

US Dept of HHS, 2017.

Types of immunosuppressive agents



Patient education on irAEs

- Patients should receive information on **expected or potential irAEs** prior to treatment
- If **corticosteroids** are used to manage irAEs, patients should be counseled on their potential side effects
- Careful risk-benefit discussions should take place with patients with **autoimmune disorders**

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General guidance for all irAEs

- **Baseline tests** should include CBC with differential, CMP, TSH, and fT4.
  - Additional tests may include urinalysis and EKG.
  - CBC, CMP, TSH and fT4 should be performed intermittently throughout therapy.
- Diagnostics should attempt to **rule out other etiologies**, but irAE treatment should be initiated as clinically appropriate.
- **Specialists** should be consulted for all toxicities of grade 3+ or those that do not respond to steroids.

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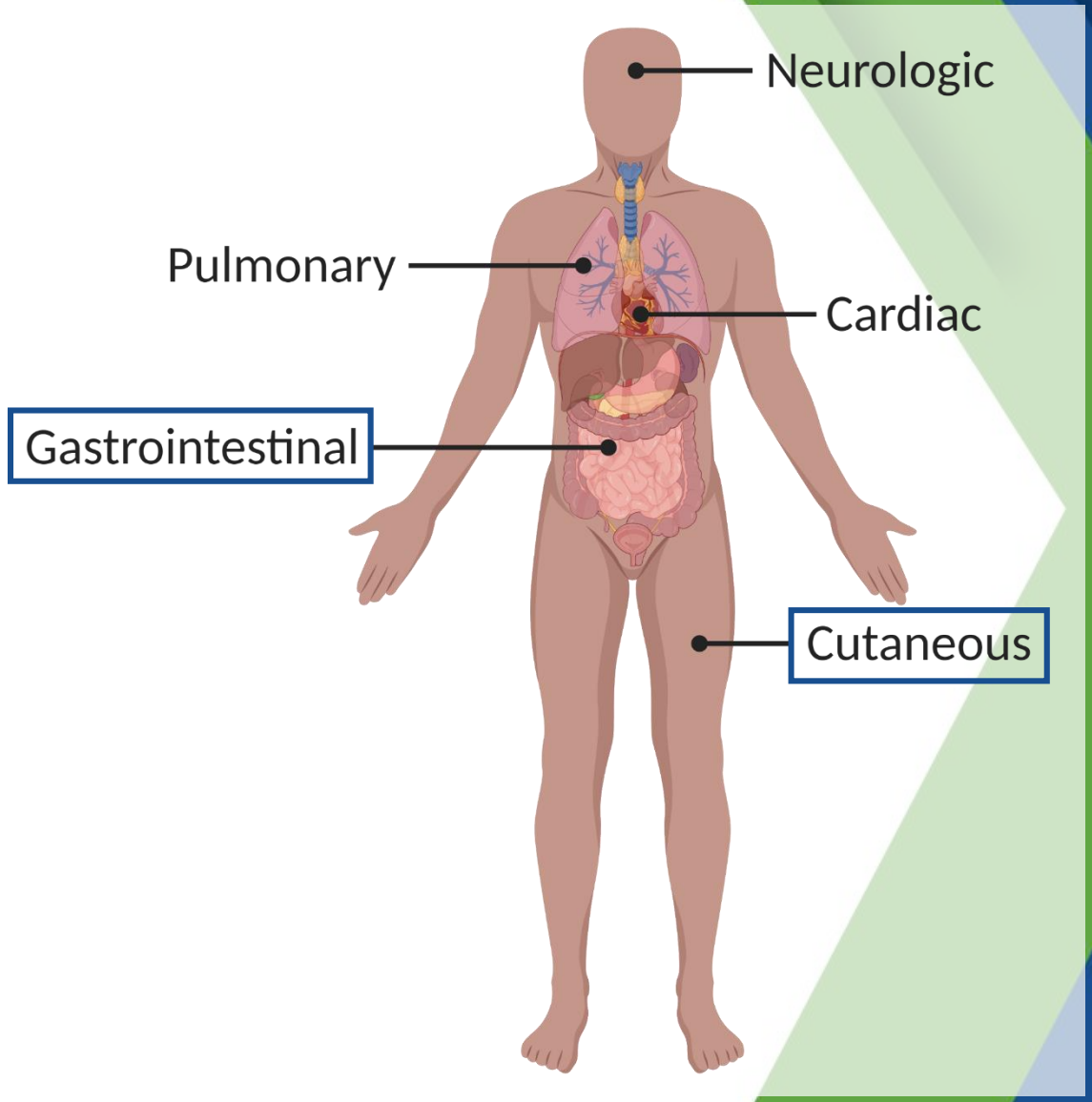
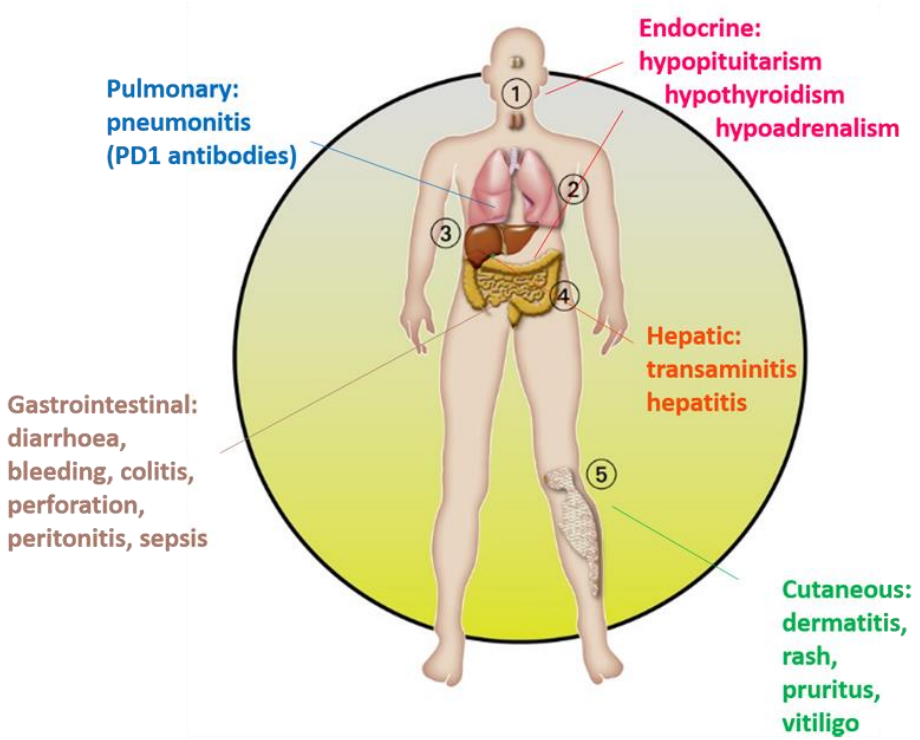


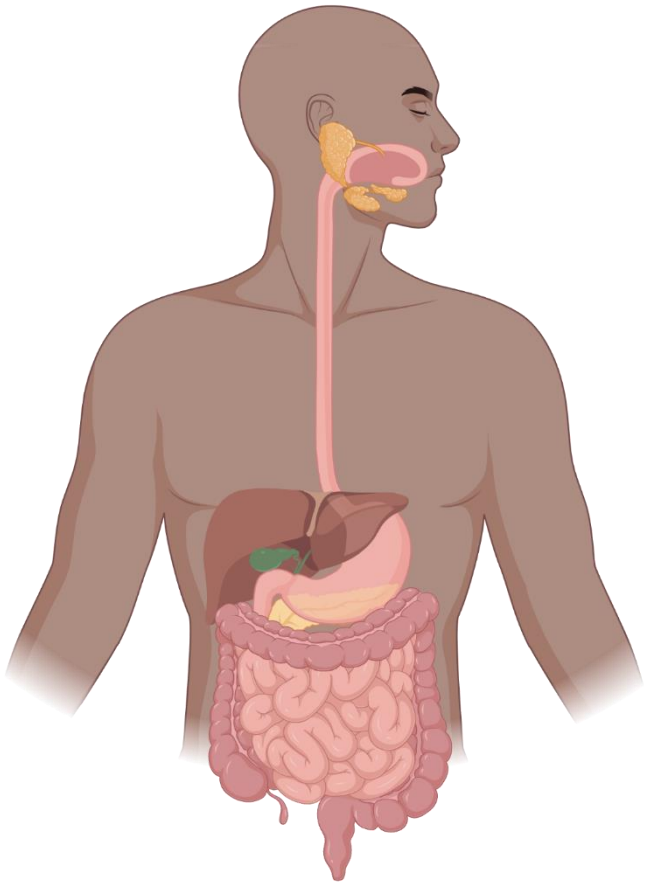
Most frequent irAEs

	Grade 3-4 AEs %	% of Pts who permantely discontinued for any grade
Ipilimumab 3 mg/kg[1]	27	15.4
Ipilimumab 10 mg/kg[1]	34	31
Nivolumab[2]	13	6
Pembrolizumab 2 mg/kg[3]	13.5	4.5
Ipilimumab/Nivolumab[4]	56.5	38.7



1. Ascierto et al. ESMO 2016
2. Atkinson et al. SMR 2015
3. Hamid ESMO 2016
4. Wolchock et al ASCO 2016

Immune-related gastrointestinal adverse events



GI toxicity	Symptoms
Gastritis	Upper stomach pain; nausea; vomiting
Enteritis	Nausea; vomiting; diarrhea
Colitis	Diarrhea; abdominal pain; mucous or blood in stool
Hepatitis	Elevated liver enzymes
Pancreatitis	Upper abdominal pain, often post-prandial; occasional diarrhea
Cholangitis	Fever; chills; abdominal pain

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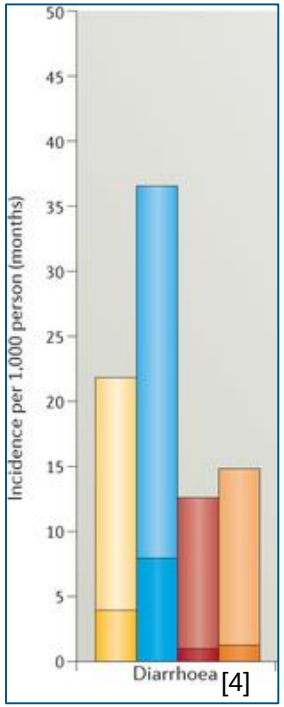
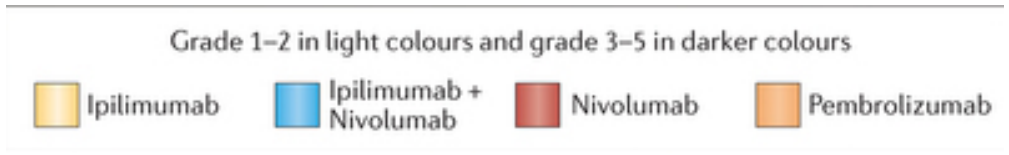
Colitis/Diarrhea

Similar to Ulcerative colitis which is an idiopathic, chronic inflammatory disorder of the colonic mucosa, which starts in the rectum and generally extends proximally in a continuous manner through part of, or the entire, colon.

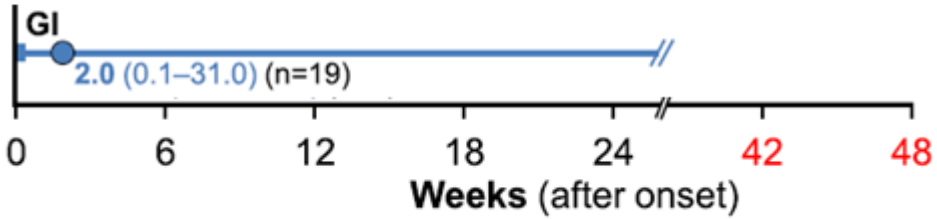
	Median Time to onset colitis
Anti-PD-1/PD-L1	6-18 weeks [1]
Ipilimumab/Nivolumab	8 weeks [2]
Anti-CTLA-4	After 5 weeks [3]

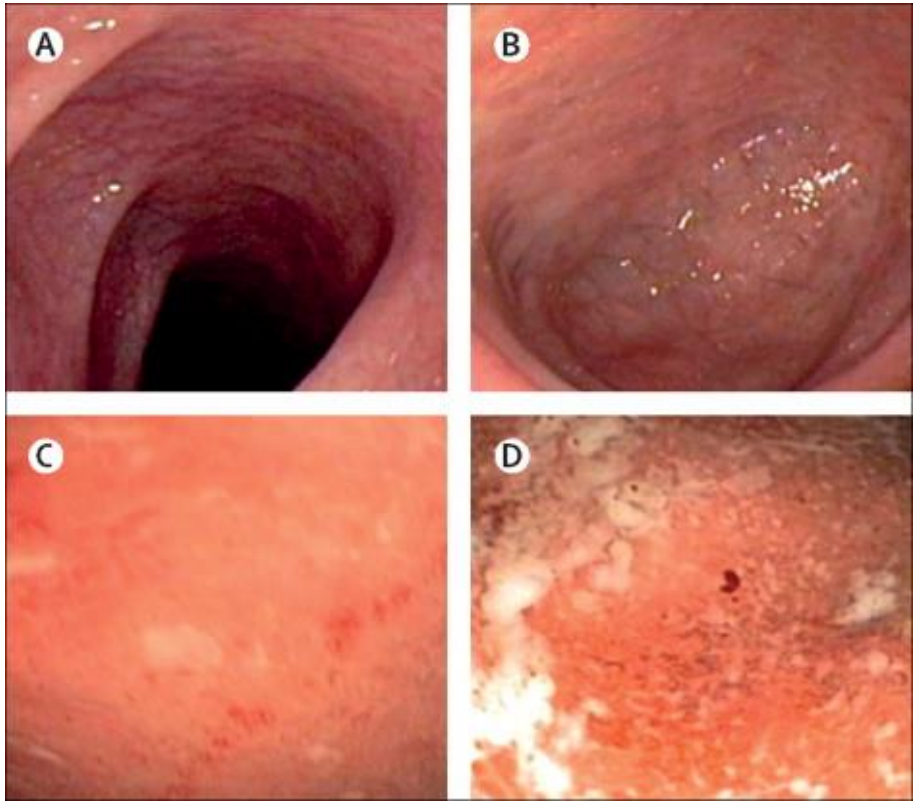


[4]



TIME TO RESOLUTION: 2 weeks after onset (median) [1]





Ordas I et al. The Lancet 2012

1. Thomas K. Eigentler et al. Cancer treatment reviews 45 (2016) 7-18
2. Hodi FS, et al. *J Clin Oncol*. 2015;33(15 suppl):abstr 9004.
3. Helena Linardou et al. Ann Transl Med 2016;4(14):272
4. Boutros C et al. *Nature Reviews Clinical Oncology* 2016

Diagnosis of diarrhea and colitis

- Typical onset 5-10 weeks
- May lead to colonic perforation, ischemia, necrosis, bleeding and toxic megacolon
- Diagnostic workup:
  - Grade 1: CBC, CMP and fecal lactoferrin
  - Grade 2+: fecal calprotectin, TSH and stool infectious analysis
  - Grade 3+: endoscopic evaluation with biopsy or CT scan

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Management of colitis

Grade 1	Grade 2	Grade 3	Grade 4
• Close observation	• Withhold ICIs • Front-line corticosteroids at 1 mg/kg/day prednisone equivalent • May re-challenge once grade ≤ 1 and <10 mg/day prednisone	• Withhold ICIs • Front-line corticosteroids at 1-2 mg/kg/day prednisone equivalent • May re-challenge once grade ≤ 1 and <10 mg/day prednisone	• Withhold and potentially discontinue ICIs • Front-line IV corticosteroids
• Once symptoms improve to grade 1 or less, taper steroids over four weeks • If no response to corticosteroids within 3-5 days, if symptoms recur upon tapering, or if there is severe ulceration on colonoscopy, administer infliximab (3 doses) • If symptoms persist after two doses of infliximab, administer vedolizumab (3 doses) • Patients can be re-challenged with ICIs, but should be monitored closely given risk of recurrence			

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Diagnosis and management of nausea/ vomiting

- May be symptomatic of other conditions like infection, metastases or other irAEs
- Grade 2+ may be managed with antiemetics if not deemed to be a symptom of other conditions – corticosteroids not recommended
- If no improvement within a week, esophagogastroduodenoscopy may be considered

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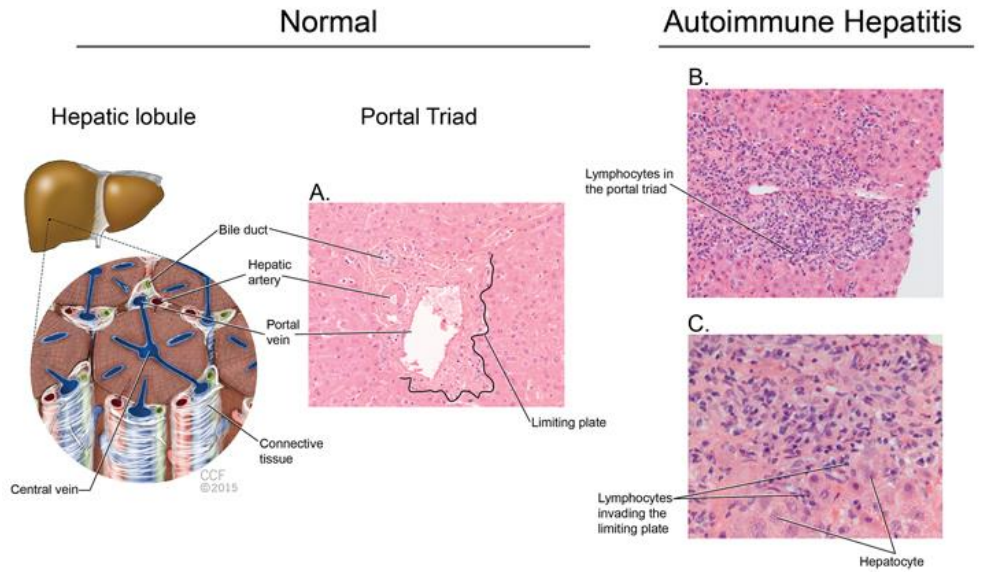
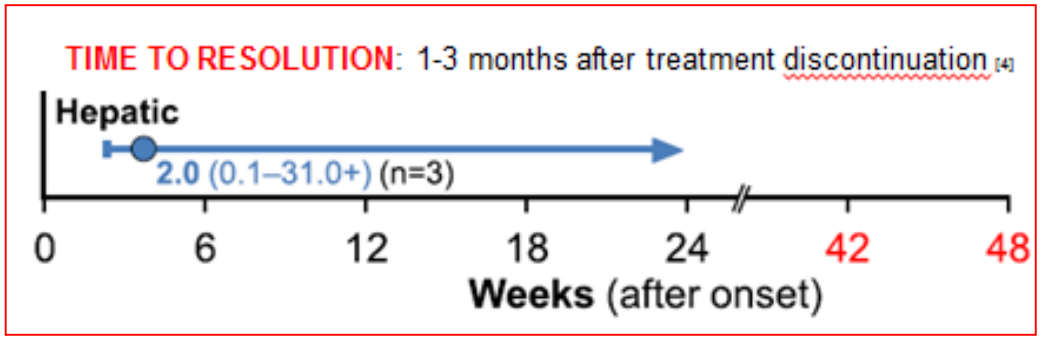
Autoimmune Hepatitis

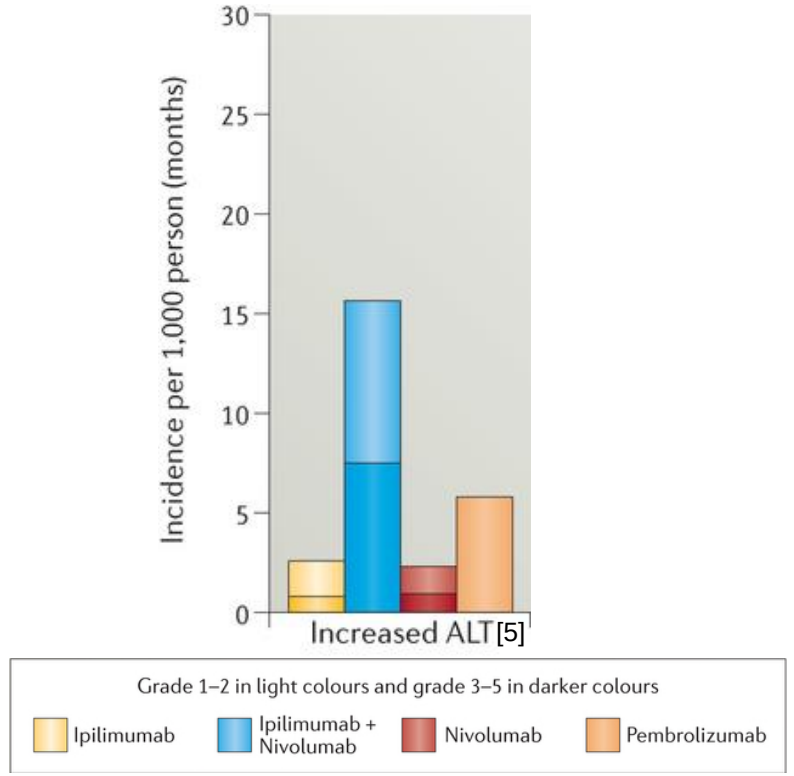
Hepatitis occurs in [1]:

- 5%–10% (of which 1%–2% is grade 3) of patients during therapy with ipilimumab, nivolumab and pembrolizumab
- 25%–30% (of which 15% is grade 3) of those treated with the combination of ipilimumab 3 mg/kg and nivolumab 1 mg/kg

	Median Time to onset hepatitis
Anti-PD-1/PD-L1 [2]	14,1 weeks (1,9 – 25,1 weeks)
Ipilimumab/Nivolumab [2]	7,4 weeks (2,1 – 48 weeks)
Anti-CTLA-4 [3]	After 6 weeks

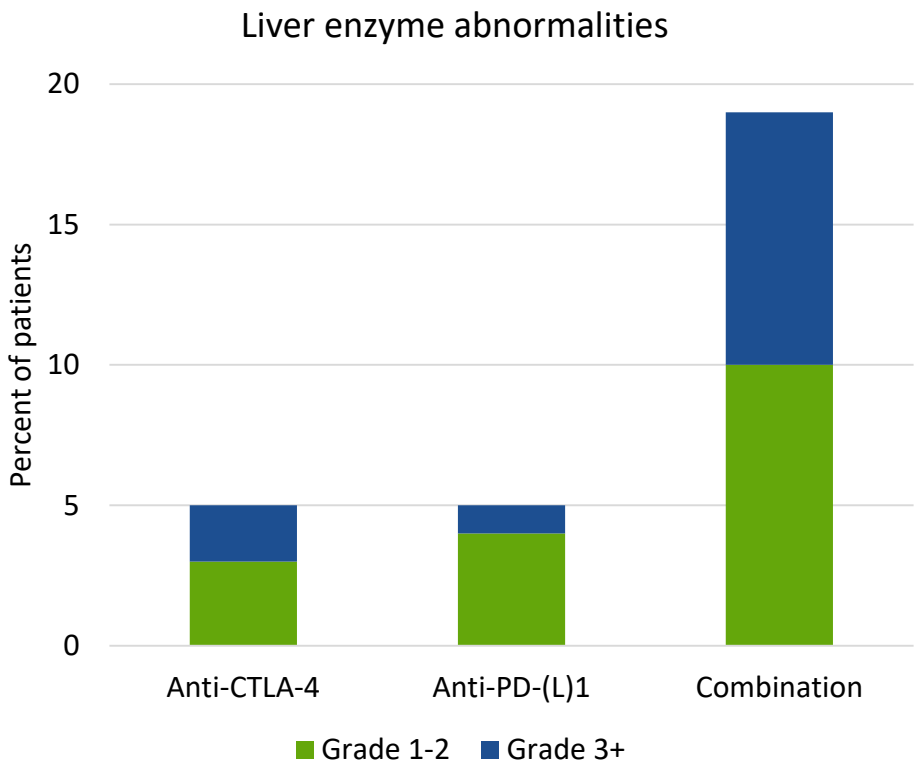






1. Larkin J, et al. N Engl J Med 2015; 373: 23–34
2. J. B. A. G. Haanen et al. Annals of Oncology 28 (Supplement 4): iv119–iv142, 2017
3. Helena Linardou et al. Ann Transl Med 2016;4(14):272
4. Johncilla M, et al. Am J Surg Pathol 2015; 39: 1075–84
5. Boutros C et al. *Nature Reviews Clinical Oncology* 2016

Incidence and grading of hepatitis



	Grade 1	Grade 2	Grade 3	Grade 4
ALT/AST increased	>1 – 3 x ULN or baseline	3 - 5 x ULN or baseline	5 -20 x ULN or baseline	>20 x ULN or baseline
Bilirubin increased	>1 – 1.5 x ULN or baseline	1.5 – 3 x ULN or baseline	3 – 10 x ULN or baseline	>10 x ULN or baseline
ALKP increased	>1-2.5 x ULN or baseline	2.5 – 5 x ULN or baseline	5 – 20 x ULN or baseline	>20 x ULN or baseline

ULN: upper limit of normal

- Note that cancer patients may have elevated levels even before treatment, particularly those with GI tumors.
- Liver function tests should be checked prior to each ICI infusion, since hepatitis may be otherwise asymptomatic.

Arnaud-Coffin, Int J Cancer 2019

Diagnosis and management of hepatitis

Grade 1	Grade 2	Grade 3	Grade 4
• Liver function tests weekly	• Liver function tests weekly • Prednisone 0.5-1 mg/kg/day	• Liver function tests every 1-2 days • Withhold ICIs • Methylprednisolone 1-2 mg/kg/day	• Liver function tests every 1-2 days • Discontinue ICIs • Methylprednisolone 1-2 mg/kg/day

- Diagnostic testing may include ALT, AST, alkaline phosphatase, prothrombin time/international normalized ratio, serum bilirubin, iron studies, autoimmune hepatitis panel and viral hepatitis panel
- Should also check for metastatic disease to liver
- Taper steroids over 4-6 weeks once LFTs revert to grade $\leq$ 1
- If LFTs do not improve or recur after taper, may administer mycophenolate mofetil or tacrolimus
- Infliximab should not be used, given risk for hepatotoxicity

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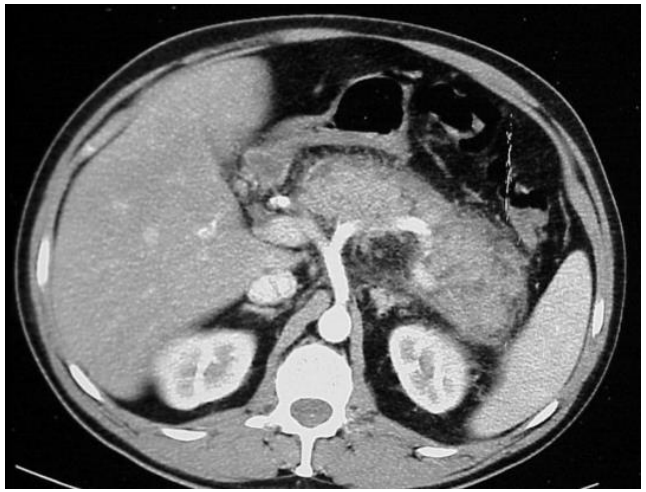
Pancreatitis

Pancreatitis is a clinical diagnosis in which two of the three components are present [1]:

- Elevation in amylase or lipase to 3X the upper limit of normal (ULN)
- Characteristic symptoms of severe epigastric pain
- Radiographic findings

Table 1. Rate of grade 3–4 amylase and lipase elevations, clinical pancreatitis events, steroid usage, and patients who had dose delays for elevated amylase or lipase [2]

Immune-related adverse events	CA209004 (n = 39) No. (%)	CA209069 (n = 16) No. (%)	CA209218 (n = 64) No. (%)	Total (n = 119) No. (%)
Grade 3 amylase	4 (10.3)	0	3 (4.7)	7 (5.9)
Grade 4 amylase	0	0	3 (4.7)	3 (2.5)
Grade 3 lipase	6 (15.4)	3 (18.8)	14 (21.9)	23 (19.3)
Grade 4 lipase	5 (12.8)	0	4 (6.3)	9 (7.6)
Grade ≥3 amylase + lipase	4 (10.3)	0	6 (9.8)	10 (8.4)
Pancreatitis	1 (2.6)	0	1 (1.6)	2 (1.7)
Steroid treatment for asymptomatic elevated amylase/lipase	5 (12.8)	0 (0)	4 (6.3)	9 (7.6)
Dose delay for asymptomatic elevated amylase/lipase	6 (15.4)	1 (6.25)	8 (12.5)	15 (12.6)



Increase in amylase and lipase may reflect T-cell-mediated inflammation even of nonpancreas organs that produce these enzymes [2].

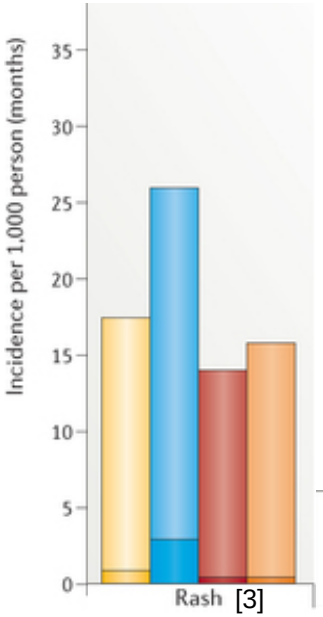
Given the low incidence of pancreatitis and the discrepancy between laboratory abnormalities and clinical pancreatitis, clinical practice is to only evaluate amylase and lipase in patients who are clinically suspected to have pancreatitis [2]

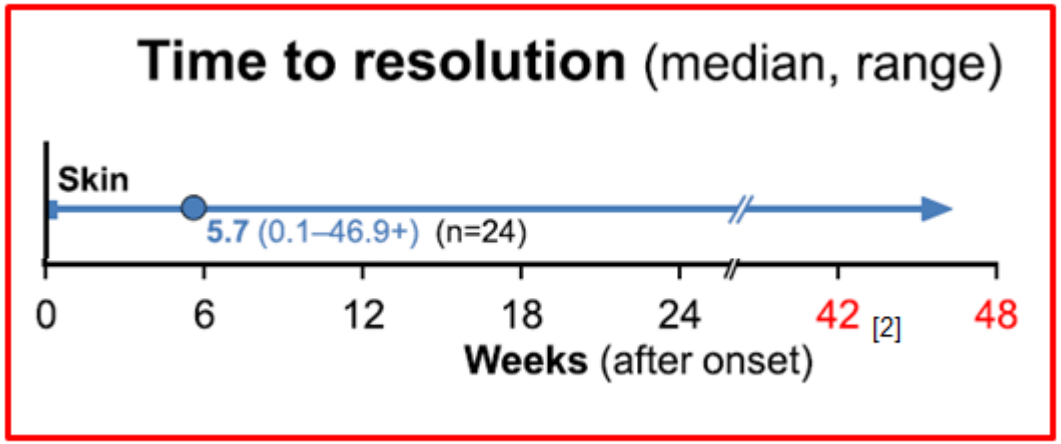
1. Banks PA, et al. Gut. 2013;62(1):102–111.
2. C. F. Friedman et al. JNCI (2017) 109(4): djw260

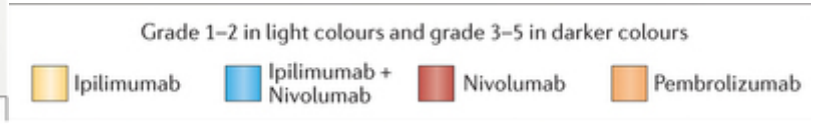
Rash and skin toxicities

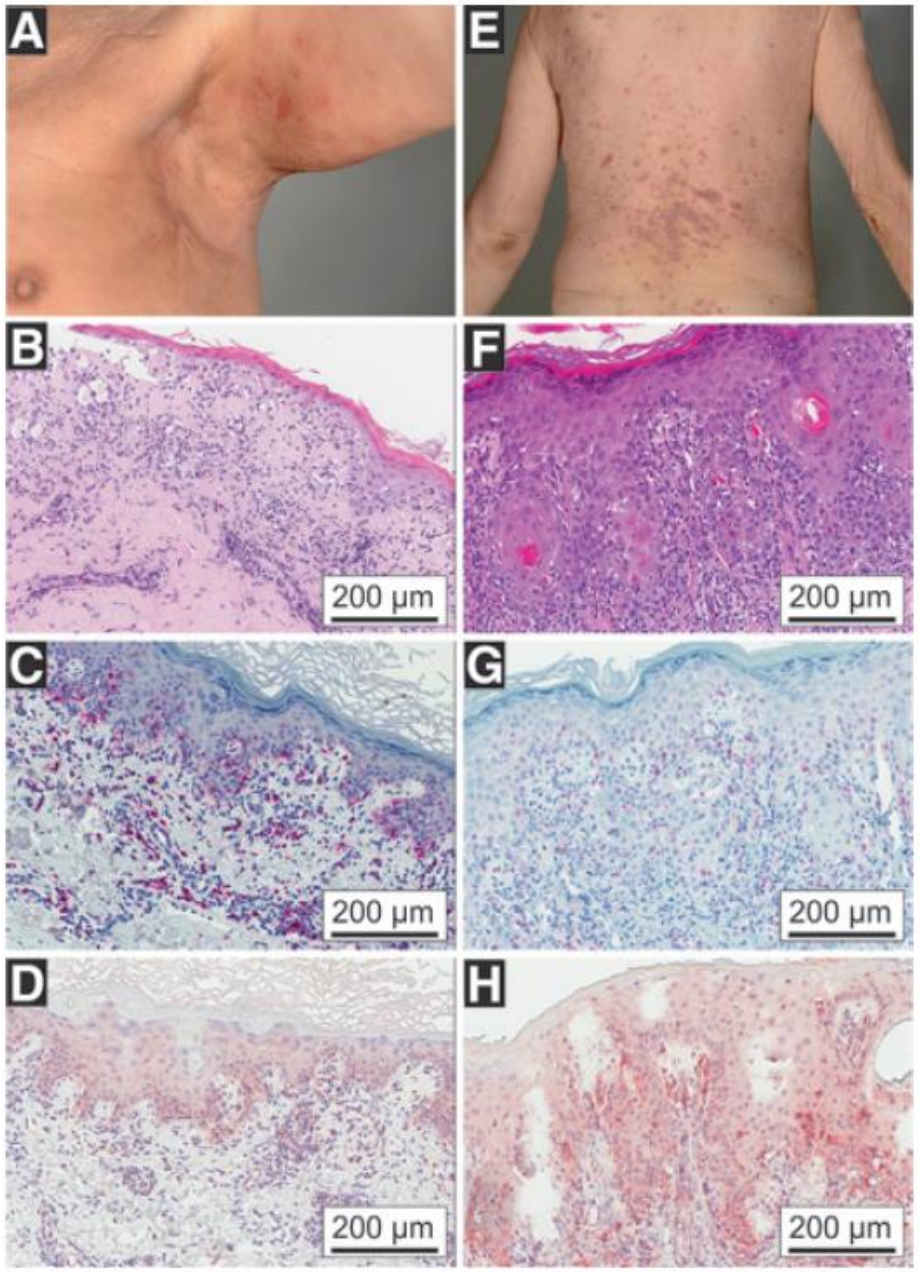
	Time to onset skin toxicities
Anti-CTLA-4	3-6 weeks [1]
Anti-PD-1/PD-L1	4-23 weeks [2]
Ipilimumab/nivolumab	During the induction phase [3]

➢ **TIME TO RESOLUTION**: 5,7 weeks after onset (median) [2]









1. Helena Linardou et al. Ann Transl Med 2016;4(14):272
2. T.K. Eingentler et al. Cancer treatment reviews 45 (2016) 7-18
3. Boutros C et al. *Nature Reviews Clinical Oncology* 2016

Cutaneous irAEs

- One of the **earliest** irAEs to appear, on average 3-4 weeks after start of treatment.
- Often grade 1-2, but **serious** irAEs like Stevens-Johnson syndrome, bullous rashes and toxic epidermal necrolysis may occur.
- For all grades, **referral** to a dermatologist should be considered.
- **Workup** for patients with potential ICI-related rash (grade < 3) should include CBC with differential, CMP, assessment of the BSA involved by the rash, assessment of special features, and patient history of allergy or atopy.
- Grade 3+ should also consider a **skin biopsy**.
- Additional tests may be needed for **severe toxicities**, and ICIs should be held.

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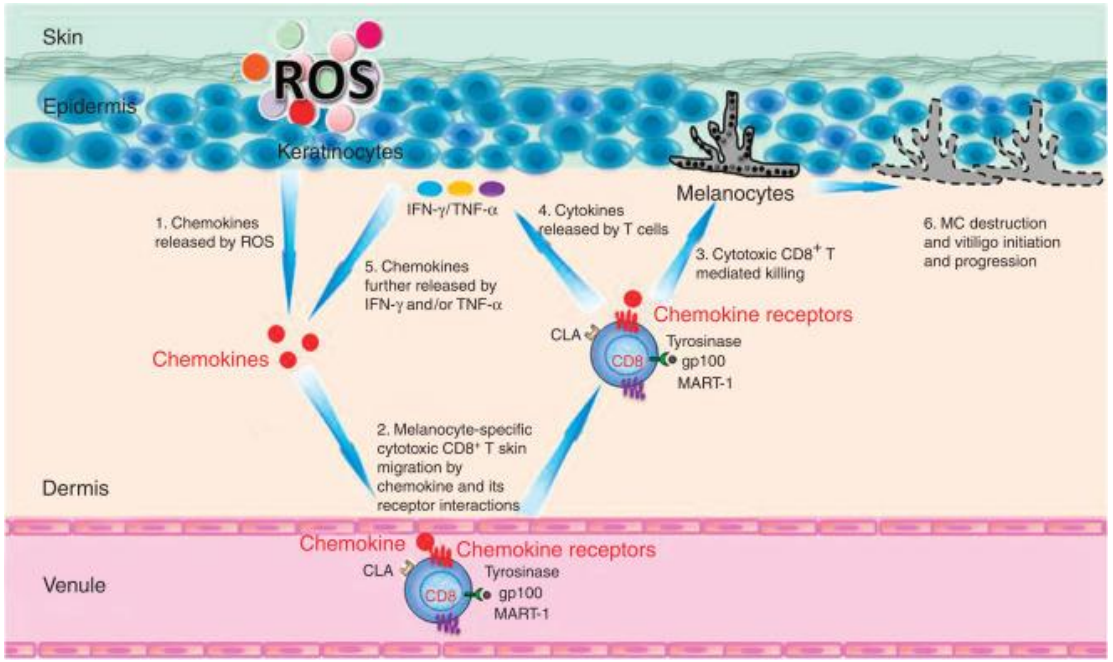
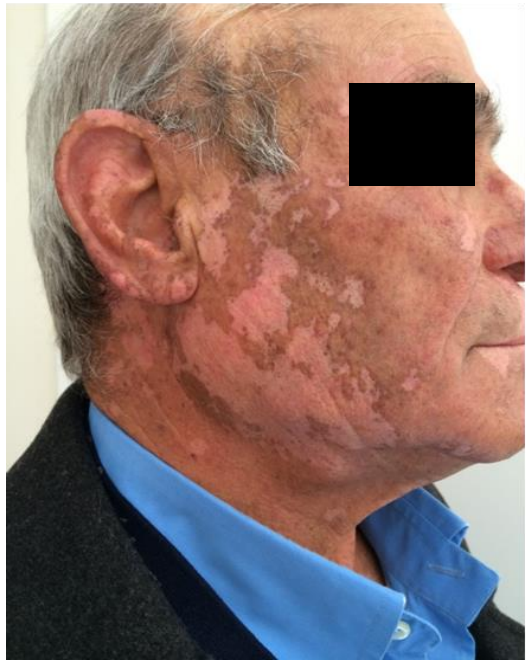
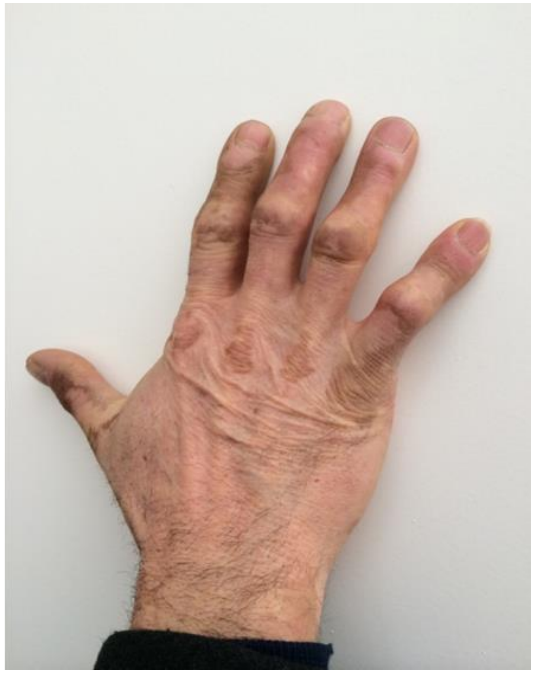
Vitiligo

	Incidence [3]
Nivolumab	7,5%
Pembrolizumab	8,3%

- Onset time from start IO: 2- 3 months [1]
- Is predictive of a good overall response In patients with metastatic melanoma [2]
- No definitive treatment exists for immune therapy–related vitiligo.



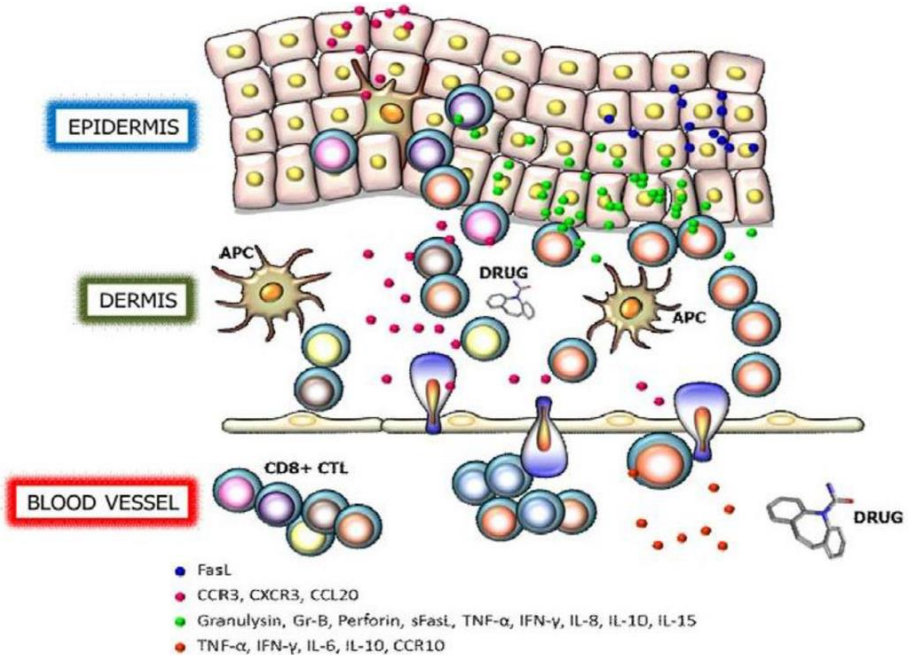


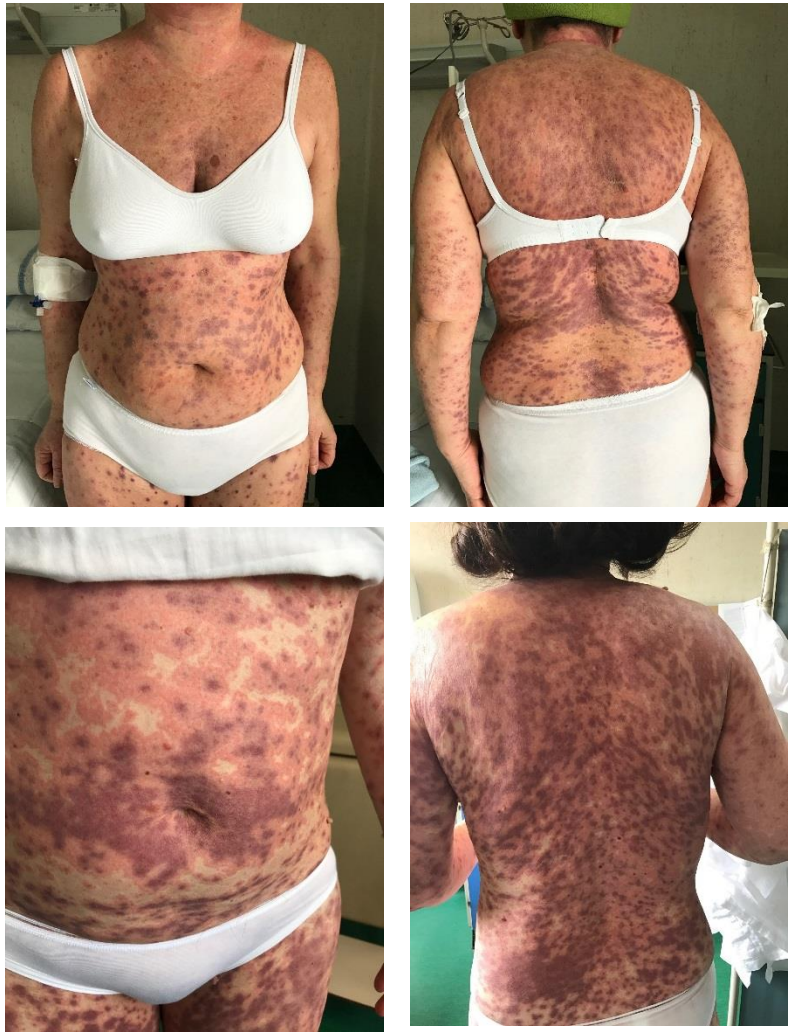


1. Sibaud V et al. Curr Opin Oncol 2016; 28: 254–63.
2. Hua C et al. JAMA Dermatol 2016; 152: 45–51
3. Belum VR, etal..Eur J Cancer 2016; 60:1 2–25.

Stevens-Johnson Syndrome

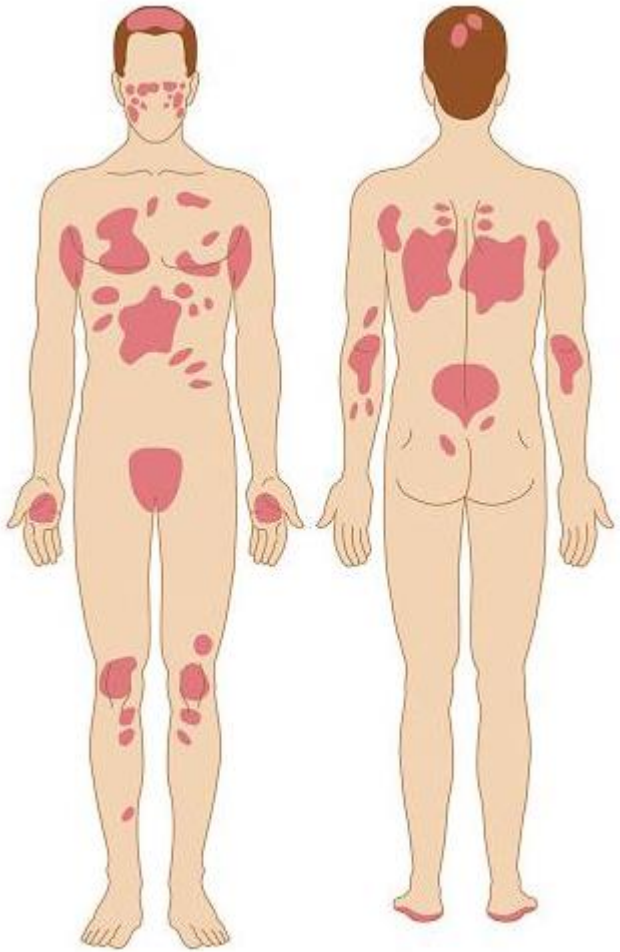
A serious systemic (body-wide) hypersensitive reaction with a characteristic rash involving the skin and mucous membranes, including the buccal mucosa, conjunctiva, and genital areas.

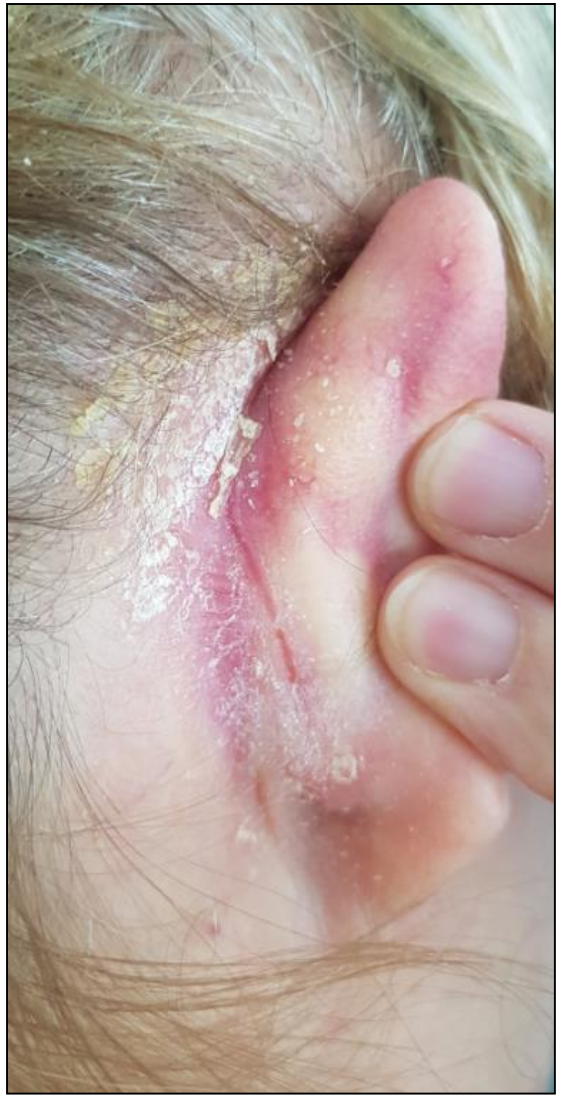


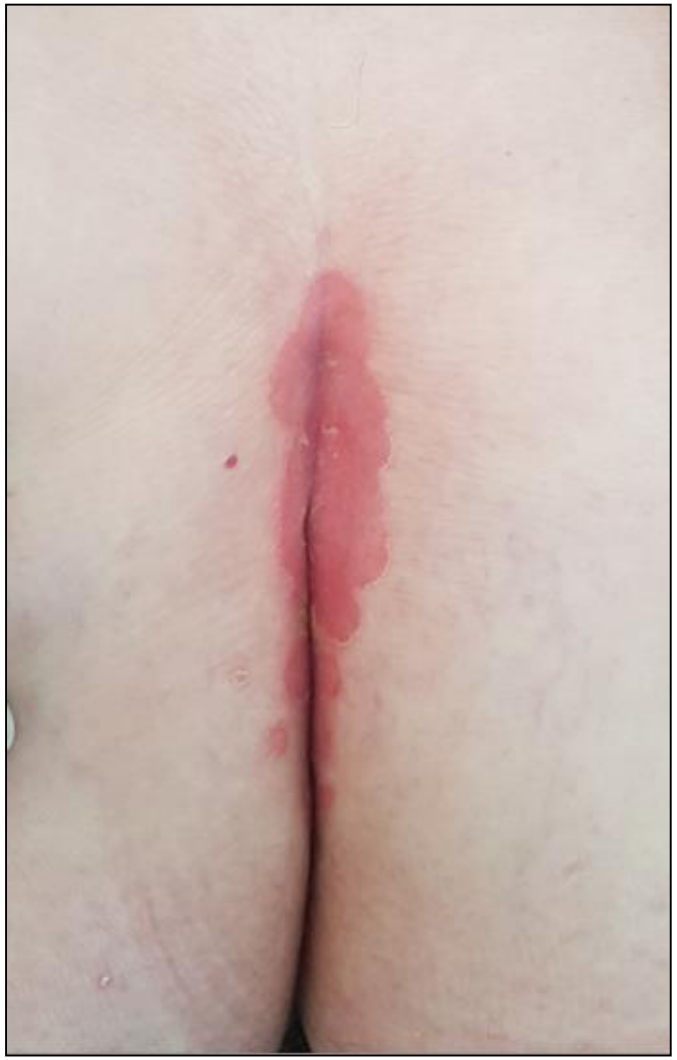


Psoriasis – Clinical presentation

Clinical types were plaque (53.3%), scalp (n20.0%), gutatte (20.0%) psoriasis, or sebopsoriasis (6.8%) [1].







1. Bonigen J. Et al. Anti-PD1-induced psoriasis.

Management of cutaneous irAEs

- GABA agonists may be used for pruritus without rash.
- Topical and oral corticosteroids are general management options.
- Dermatologic events may recur after steroid taper; therefore, dermatologic consultation and/or steroid-sparing agents are recommended.
- Rashes that do not respond to steroids should be regarded with suspicion for infection, and cultures should be obtained.

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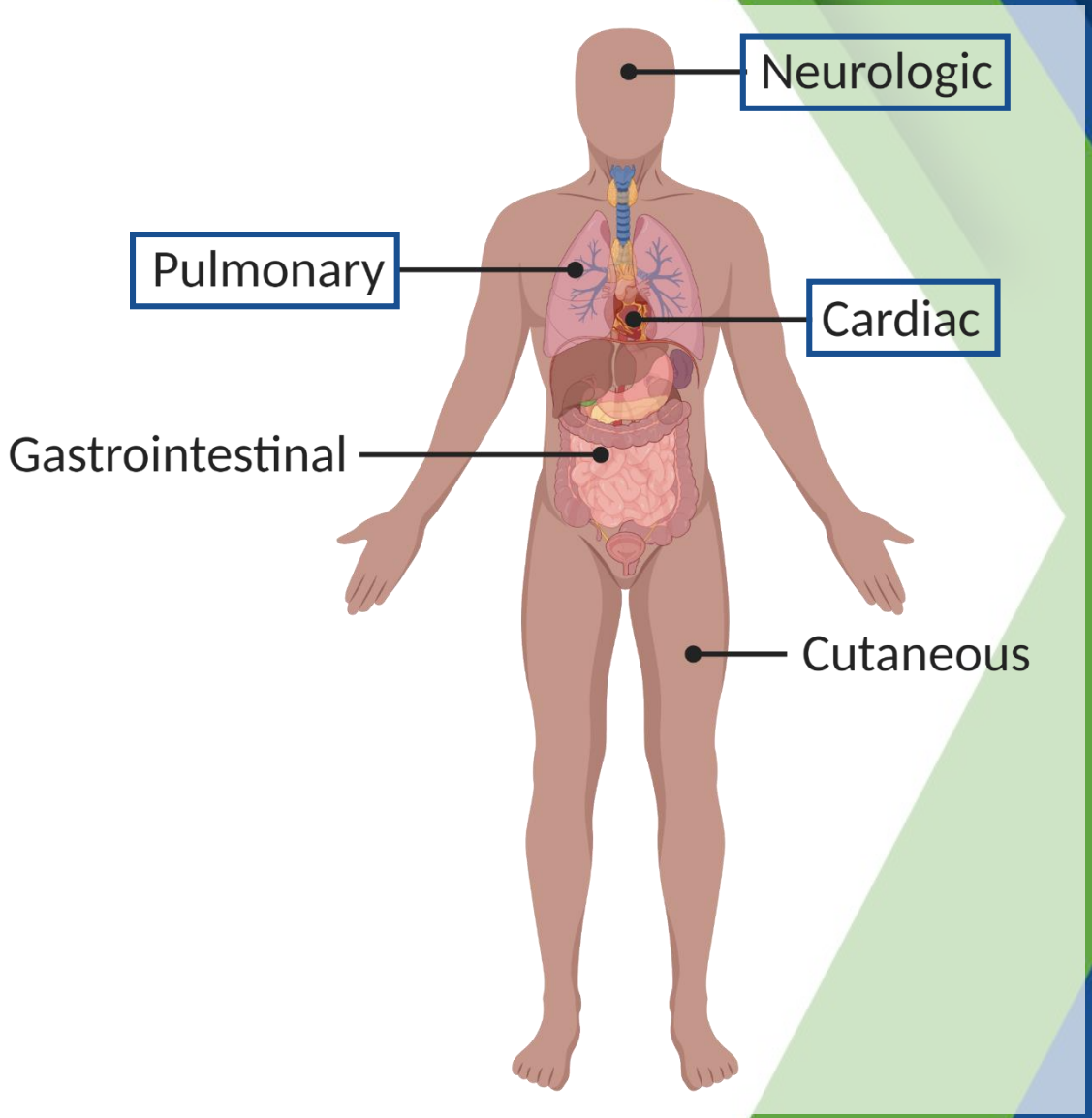
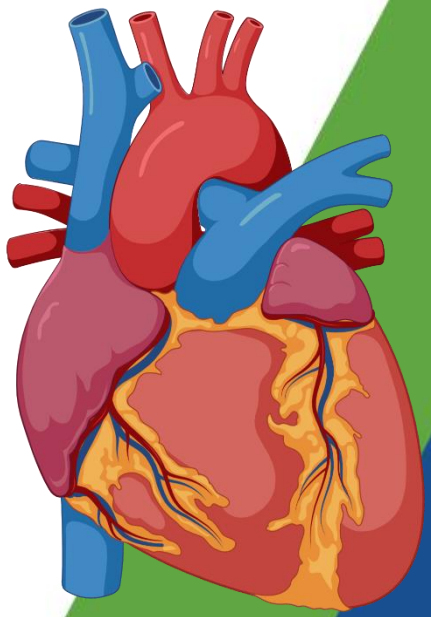
  - Pulmonary
  - Neurologic
- Other life-threatening toxicities



Presentation of myocarditis

- Uncommon (<1%), but may be life-threatening (up to 50% of cases may lead to fatality)
- Highest incidence and fatality with combination treatment
- Median onset 1 month after therapy initiation
- Symptoms include:
  - Chest pain
  - Shortness of breath
  - Arrhythmias
  - Fatigue



Salem, Lancet Oncol 2018
Brahmer, J Immunother Cancer 2021

Diagnosis and management of myocarditis

Diagnosis

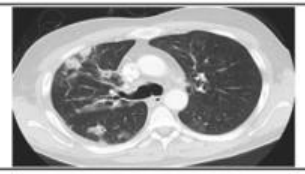
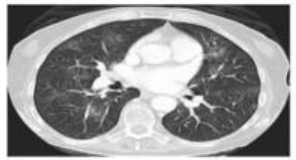
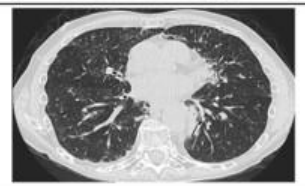
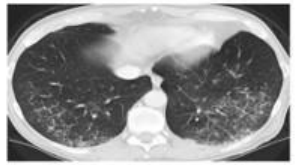
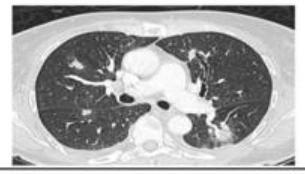
- Rapid diagnosis and management is critical
- Consult with a cardiologist
- Diagnostic techniques include:
  - Troponin levels (elevated in almost all patients with myocarditis)
  - EKG
  - Cardiac MRI
  - Endomyocardial biopsy

Management

- Discontinuation of ICIs and hospitalization
- Initial high-dose corticosteroids, typically 1 g/day IV methylprednisolone
- Steroid-resistant myocarditis may benefit from anti-thymocyte globulin, mycophenolate mofetil, abatacept or alemtuzumab

Bonaca, Circulation 2019
Brahmer, J Immunother Cancer 2021

Pulmonary toxicities - pneumonitis

Radiologic Subtypes	Representative Image	Description
Cryptogenic organizing pneumonia-like (n = 5, 19%)		Discrete patchy or confluent consolidation with or without air bronchograms Predominantly peripheral or subpleural distribution
Ground glass opacities (n = 10, 37%)		Discrete focal areas of increased attenuation Preserved bronchovascular markings
Interstitial (n = 6, 22%)		Increased interstitial markings, interlobular septal thickening Peribronchovascular infiltration, subpleural reticulation Honeycomb pattern in severe patient cases
Hypersensitivity (n = 2, 7%)		Centrilobular nodules Bronchiolitis-like appearance Tree-in-bud micronodularity
Pneumonitis not otherwise specified (n = 4, 15%)		Mixture of nodular and other subtypes Not clearly fitting into other subtype classifications

- Pulmonary toxicities include a range of adverse events, with varying radiological presentations
- Need to rule out differential options:
  - Disease progression
  - Immune infiltration of tumors
  - Infection (i.e. COVID-19)
  - Radiation pneumonitis
- Can be fatal, making prompt recognition and management critical

Naidoo, J Clin Oncol 2017

Presentation of pneumonitis

- Inflammation of lung tissue – symptoms include:
  - Dyspnea
  - Cough
  - Chest pain
  - Fever
  - Hypoxia
- May be asymptomatic but show inflammation on chest scans
- Median onset 2-5 months after starting ICIs

Brahmer, J Immunother Cancer 2021

Diagnosis and management of pneumonitis

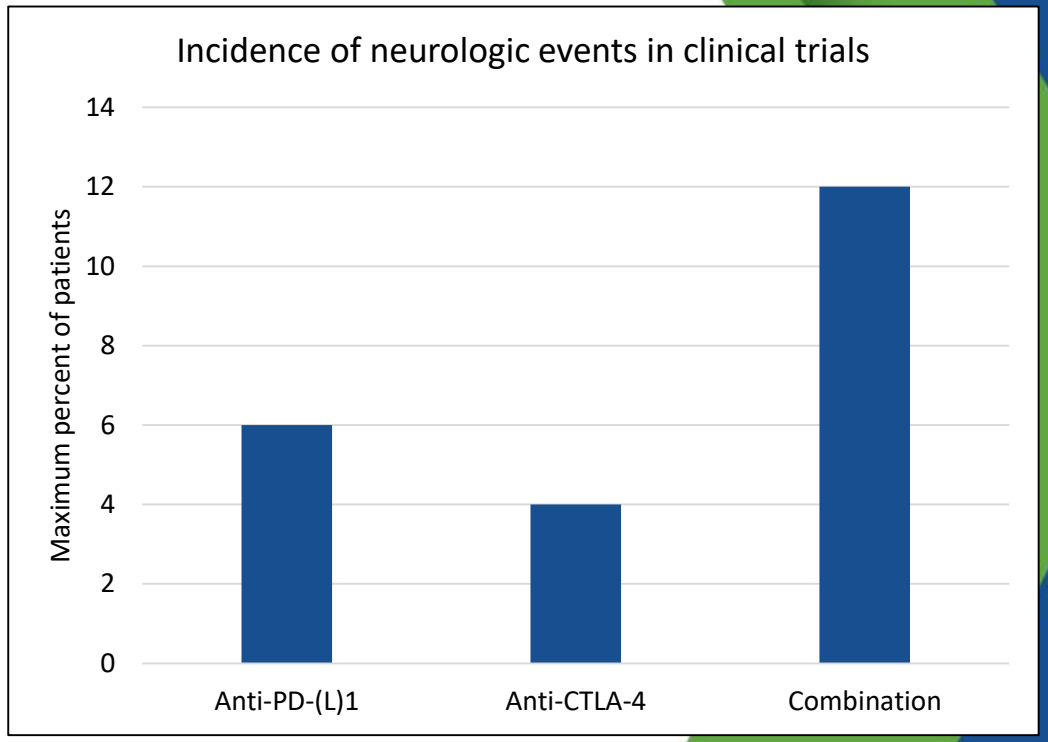
Grade 1	Grade 2	Grade 3	Grade 4
• Close observation	• Withhold ICIs • Corticosteroids 1-2 mg/kg/day prednisone equivalent	• Discontinue ICIs • Corticosteroids 1-2 mg/kg/day methylprednisolone equivalent	• Discontinue ICIs • Corticosteroids 1-2 mg/kg/day methylprednisolone equivalent

- Suspected pneumonitis should be evaluated through chest CT scan
- Pulmonary function tests may be performed as well, which should include spirometry and diffusing capacity of the lungs for carbon monoxide (DLCO)
- If symptoms do not respond to corticosteroids within 72 hours or are life-threatening, additional therapies include:
  - Mycophenolate mofetil
  - hdIVIG
  - Cyclophosphamide
  - Tocilizumab
  - Infliximab

Brahmer, J Immunother Cancer 2021

Neurologic toxicities

- Majority of neurologic events are grade 1-2 and non-specific
- Neurologic consult should always take place, regardless of severity
- Potential severe neurotoxicities include:
  - Myasthenia gravis
  - Encephalitis
  - Peripheral neuropathy
  - Aseptic meningitis



Cuzzubbo, Eur J Cancer 2017;
Brahmer, J Immunother Cancer 2021

Myasthenia gravis

Diagnosis

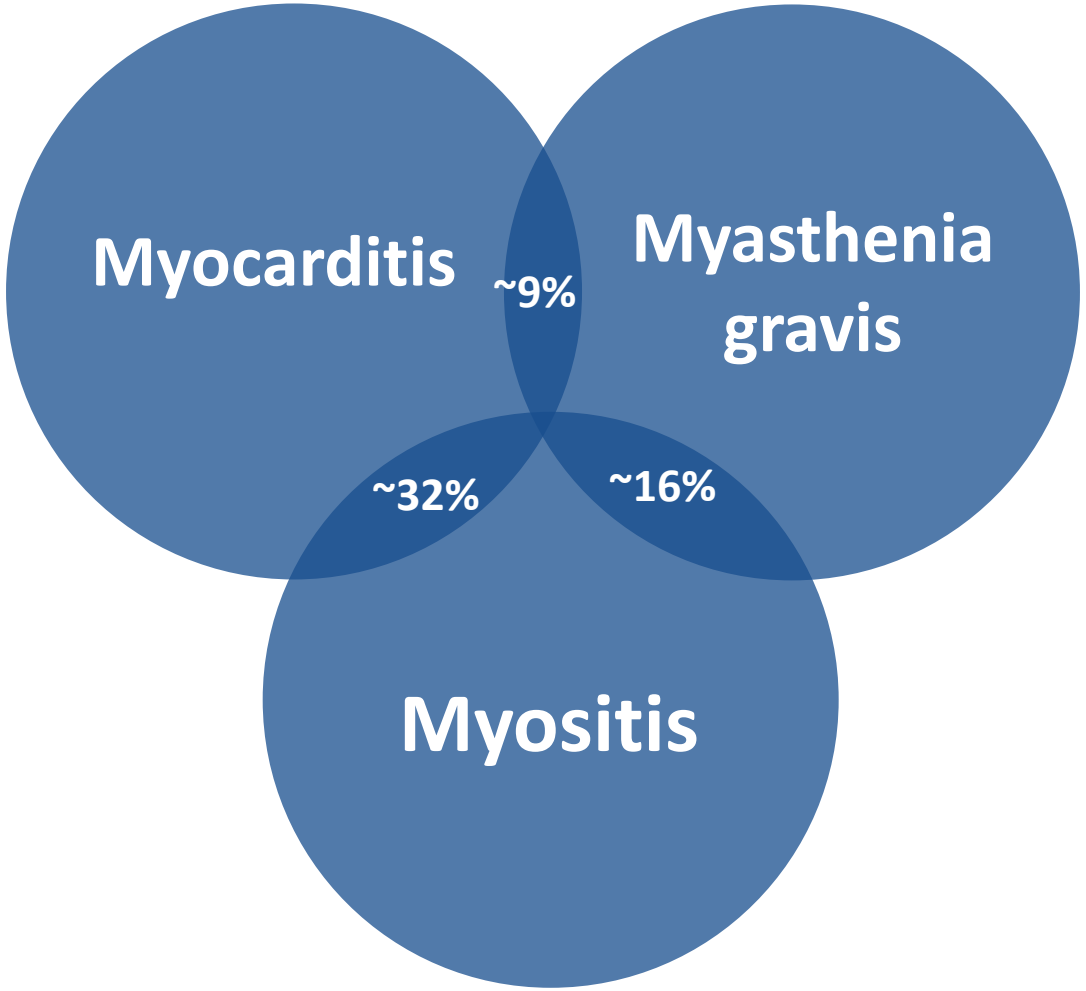
- Not very common, but high potential for patient fatality
- Patients may present with:
  - Fatigable or fluctuating muscle weakness, often in proximal muscles
  - Ptosis
  - Facial weakness
  - Difficulty swallowing
  - Respiratory compromise
- **May co-occur with myositis and/or myocarditis**

Management

- Discontinue ICIs
- Frequent pulmonary assessments
- Corticosteroids and pyridostigmine with IVIG or PLEX
- Grade 3+: hospital admission and potential ICU-level monitoring

Brahmer, J Immunother Cancer 2021

Overlapping toxicities



Moreira et al, *Eur J Cancer* 2019
Johnson, J Immunother Cancer 2019

Webinar outline

- Introduction to the Guideline
- General irAE management
- Managing common irAEs
  - Gastrointestinal
  - Cutaneous
- Managing serious irAEs
  - Cardiac
  - Pulmonary
  - Neurologic
- Other life-threatening toxicities

Stevens-Johnson Syndrome
Type 1 diabetes mellitus
Hemaphagocytic lymphohistiocytosis

Stevens-Johnson syndrome / toxic epidermal necrolysis

- Rare and can be **life-threatening**
- Severe **immune reaction** in the skin
- **Mucosal** involvement is common
- Reported with **anti-PD-1 and anti-CTLA-4** treatments
- May be rapid and **acute**, or **progress** from less severe event
- **Skin biopsy** and serum antibodies should be tested
- Management includes **holding ICIs** and administering **steroids**

Brahmer, J Immunother Cancer 2021

Type 1 diabetes mellitus

- **ICI-induced diabetes** occurs in <1-2% of patients treated with anti-PD-(L)1 therapies
- Initial presentation is **fulminant T1DM and diabetic ketoacidosis**
- **Autoantibodies** present in majority of cases
- Requires **emergent management**
- Life-long **insulin management** usually necessary

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Hemaphagocytic lympohistiocytosis

- Involves inappropriate **macrophage activation**
- **Diagnosis** includes cytopenias, hyperferritinemia, fever, splenomegaly, coagulopathy, LFT abnormalities, elevated IL-2R
- Rare, but more common with **anti-CTLA-4** treatment
- Hematological **consultation** recommended
- **Management** includes steroids, immunosuppressives (etoposide, tocilizumab)

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Conclusions

- Immunotherapy has become a standard tool in the management of cancer patients
- Understanding the unique side effects of immunotherapy is critical for optimal management
- Immunotherapy toxicities can impact patients at any point in their therapy
- Multidisciplinary team management is important for managing patients

Society for Immunotherapy of Cancer

Cancer Immunotherapy GUIDELINES

Practical Management Pearls for Immune Checkpoint Inhibitor-related Adverse Events

September 16, 2021, 11:30 a.m. – 12:30 p.m. ET

Immunotherapy for the Treatment of Urothelial Cancer Guideline Overview

August 25, 2021, 5:30 – 6:30 p.m. ET

CME-, CNE-, CPE-certified

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https://www.sitcancer.org/research/cancer-immunotherapy-guidelines/webinars

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SEMINAR 5: MACROPHAGE BIOLOGY FOR ANTI-TUMOR IMMUNITY – October 7, 2021, 10:30 a.m. - 12:30 p.m. ET

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