

癌症免疫檢查點抑制劑使用於非小細胞肺癌及泌尿道上皮癌第一線用藥時，須另檢附

下列無法接受化學治療條件其中一項佐證資料：

請勾選無法接受化學治療之條件，並於後附表格對應之評估項目圈選或填寫評估結果

CTCAE (the common terminology criteria for adverse events) v4.0 grade ≥ 2 audiometric hearing loss

CTCAE v4.0 grade ≥ 2 peripheral neuropathy

CIRS (the cumulative illness rating scale) score >6 , score: _____

CTCAE評估表範例

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0

Ear and labyrinth disorders					
	Grade				
Adverse Event	1	2	3	4	5
Hearing impaired	<p>Adults enrolled on a Monitoring Program (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift of 15 - 25 dB averaged at 2 contiguous test frequencies in at least one ear.</p> <p>Adults not enrolled in Monitoring Program: Subjective change in hearing in the absence of documented hearing loss.</p> <p>Pediatric (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift >20 dB at 8 kHz in at least one ear.</p>	<p>Adults enrolled in Monitoring Program (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift of >25 dB averaged at 2 contiguous test frequencies in at least one ear.</p> <p>Adults not enrolled in Monitoring Program: hearing loss but hearing aid or intervention not indicated; limiting instrumental ADL.</p> <p>Pediatric (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift >20 dB at 4kHz and above in at least one ear.</p>	<p>Adults enrolled in Monitoring Program (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift of >25 dB averaged at 3 contiguous test frequencies in at least one ear; therapeutic intervention indicated.</p> <p>Adults not enrolled in Monitoring Program: hearing loss with hearing aid or intervention indicated; limiting self care ADL.</p> <p>Pediatric (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): hearing loss sufficient to indicate therapeutic intervention, including hearing aids; threshold shift >20 dB at 3 kHz and above in at least one ear; additional speech language related services indicated.</p>	<p>Adults: Decrease in hearing to profound bilateral loss (absolute threshold >80 dB HL at 2 kHz and above); non-servicable hearing.</p> <p>Pediatric: Audiologic indication for cochlear implant and additional speech language related services indicated.</p>	-
Nervous system disorders					
	Grade				
Adverse Event	1	2	3	4	5
Definition: A disorder characterized by functional disturbances of sensory neurons resulting in abnormal cutaneous sensations of tingling, numbness, pressure, cold, and warmth that are experienced in the absence of a stimulus.					
Peripheral motor neuropathy	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; assistive device indicated	Life-threatening consequences; urgent intervention indicated	Death
Adverse Event	1	2	3	4	5
Definition: A disorder characterized by inflammation or degeneration of the peripheral motor nerves.					
Peripheral sensory neuropathy	Asymptomatic; loss of deep tendon reflexes or paresthesia	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death

備註：本表摘自 http://www.eortc.be/services/doc/ctc/ctcae_4.03_2010-06-14_quickreference_5x7.pdf

CIRS評估表範例

Cumulative Illness Rating Scale- Geriatric Version (CIRS-G) (適用於成人及老年人)

System/Description (Only <u>1</u> score is given for each system)		Rating
Cardiac		
0	No problem	
1	MI >5 years ago, occasional angina treated with meds as needed	
2	CHF compensated with meds, daily antianginal meds, left ventricular hypertrophy, atrial fibrillation, bundle branch block, daily antiarrhythmic drugs	
3	MI ≤5 years ago, abnormal stress test, or past PTCA or CABG	
4	Marked activity restriction secondary to cardiac status (i.e., unstable angina or intractable CHF)	
Vascular		
0	No problem	
1	Hypertension compensated with salt restriction and weight loss, cholesterol >200 mg/dL	
2	Daily antihypertensive meds, one symptom of atherosclerotic disease (angina, claudication, bruit, amaurosis fugax, absent pedal pulses), aortic aneurysm <4 cm	
3	≥2 symptoms of atherosclerosis	
4	Previous vascular surgery, aortic aneurysm ≥4 cm	
Hematopoietic		
0	No problem	
1	Hemoglobin: females 10-12 g/dL, males 12-14 g/dL, anemia of chronic disease	
2	Hemoglobin: females 8 to <10 g/dL, males 10 to <12 g/dL, anemia secondary to iron/vitamin B-12/folate deficiency or chronic renal failure, total WBC 2,000-4,000	
3	Hemoglobin: females <8 g/dL, males <10 g/dL, total WBC <2,000	
4	Any leukemia or lymphoma	
Respiratory		
0	No problem	
1	Recurrent episodes of acute bronchitis, current treated asthma with inhalers as needed, cigarette smoker 10-20 pack years	
2	X-ray evidence of COPD, requires daily theophylline or inhalers, treated for pneumonia two or more times in the past 5 years, smoked 21-40 pack years	
3	Limited ambulation secondary to limited respiratory capacity, requires oral steroids for lung disease, smoked >40 pack years	
4	Requires supplemental oxygen, ≥1 episode of respiratory failure requiring assisted ventilation, any lung cancer	

System/Description (Only <u>1</u> score is given for each system)		Rating
Eyes, ears, nose, throat, and larynx		
0	No problem	
1	Corrected vision 20/40, chronic sinusitis, mild hearing loss	
2	Corrected vision 20/60 or reads newsprint with difficulty, requires hearing aid, chronic sinonasal complaints requiring medication, requires medication for vertigo	
3	Partially blind (requires an escort to venture out), unable to read newsprint, conversational hearing still impaired with hearing aid	
4	Functional blindness, functional deafness, laryngectomy, requires surgical intervention for vertigo	
Upper GI		
0	No problem	
1	Hiatal hernia, heartburn complaints treated with as-needed meds	
2	Needs daily H ₂ blocker or antacid, documented gastric or duodenal ulcer within 5 years	
3	Active ulcer, guaiac positive stools, any swallowing disorder or dysphagia	
4	Gastric cancer, history of perforated ulcer, melena or hematochezia from upper GI source	
Lower GI		
0	No problem	
1	Constipation managed with meds as needed, active hemorrhoids, status post hernia repair	
2	Requires daily bulk laxatives or stool softeners, diverticulosis, untreated hernia	
3	Bowel impaction in the past year, daily use of stimulant laxatives or enemas	
4	Hematochezia from lower GI source, currently impacted, diverticulitis flare up, status post bowel obstruction, bowel carcinoma	
Liver, pancreas, and biliary		
0	No problem	
1	History of hepatitis >5 years ago, cholecystectomy	
2	Mildly elevated LFTs ($\leq 150\%$ of normal), hepatitis within 5 years, cholelithiasis, daily or heavy alcohol use within 5 years	
3	Elevated bilirubin (total >2 mg/dL), marked elevation of LFTs (>150% of normal), requires supplemental pancreatic enzymes for digestion	
4	Clinical or lab evidence of biliary obstruction, any biliary tree carcinoma, cholecystitis, pancreatitis, active hepatitis	
Renal		
0	No problem	
1	Kidney stone passage within the past 10 years or asymptomatic kidney stone, pyelonephritis within 5	

System/Description (Only <u>1</u> score is given for each system)		Rating
	years	
2	Serum creatinine 1.5-3.0 mg/dL without diuretic or antihypertensive medication	
3	Serum creatinine >3.0 mg/dL OR serum creatinine >1.5 mg/dL on diuretic, antihypertensive, or bicarbonate therapy, current pyelonephritis	
4	Requires dialysis, renal carcinoma	
Genitourinary		
0	No problem	
1	Stress incontinence, hysterectomy, BPH without urinary symptoms	
2	Abnormal pap smear, frequent UTIs (≥ 3 in past year), urinary incontinence (non-stress) in females, BPH with hesitancy or frequency, current UTI, any urinary diversion procedure, status post TURP	
3	Prostate cancer in situ (i.e., found incidentally during TURP), vaginal bleeding, cervical carcinoma in situ, hematuria, status post urosepsis in past year	
4	Acute urinary retention, any GU carcinoma except as above	
Musculoskeletal and skin		
0	No problem	
1	Uses meds as needed for arthritis or has mildly limited activities of daily living (ADLs) from joint pathology, excised non-melanoma skin cancers, skin infections requiring antibiotics within a year	
2	Daily antiarthritic meds or use of assistive devices or moderate limitation in ADLs, daily meds for chronic skin conditions, melanoma without metastasis	
3	Severely impaired ADLs secondary to arthritis, requires steroids for arthritic condition, vertebral compression fractures from osteoporosis	
4	Wheelchair bound, severe joint deformity or severely impaired usage, osteomyelitis, any bone or muscle carcinoma, metastatic melanoma	
Neurologic		
0	No problem	
1	Frequent headaches requiring meds as needed without interference with daily activities, history of TIA phenomena (at least one)	
2	Requires daily meds for chronic headaches or headaches that regularly interfere with daily activities, status post CVA without significant residual, mild neurodegenerative disease (Parkinson's, MS, ALS, etc)	
3	Status post CVA with mild residual dysfunction, any CNS neurosurgical procedure, moderate neurodegenerative disease	
4	Status post CVA with residual functional hemiparesis or aphasia, severe neurodegenerative disease	
Endocrine and breast		
0	No problem	

System/Description (Only <u>1</u> score is given for each system)		Rating
1	Diabetes mellitus compensated with diet, obesity (BMI >30), requires thyroid hormone replacement	
2	Diabetes mellitus requiring insulin or oral agents, fibrocystic breast disease	
3	Any electrolyte disturbance requiring hospital treatment, morbid obesity (BMI >45)	
4	Brittle or poorly controlled diabetes mellitus or diabetic coma in the past year, requires adrenal hormone replacement, adrenal, thyroid, or breast carcinoma	
Psychiatric illness		
0	No problem	
1	Minor psychiatric condition or history thereof: specifically, previous outpatient mental health treatment during a crisis, outpatient treatment for depression >10 years ago, current use of minor tranquilizers for episodic anxiety (occasional usage), mild early dementia	
2	A history of major depression (by DSM) within the past 10 years (treated or untreated), mild dementia, any previous psychiatric hospitalization, any psychotic episode substance abuse history >10 years ago	
3	Currently meets DSM criteria for major depression or two or more episodes of major depression in the past 10 years, moderate dementia, current usage of daily anti-anxiety medication, currently meets DSM criteria for substance abuse or dependency, requires daily antipsychotic medication	
4	Current mental illness requiring psychiatric hospitalization, institutionalization, or intensive outpatient management (e.g. patients with severe or suicidal depression, acute psychosis or psychotic decompensation, severe agitation from dementia, severe substance abuse, etc), severe dementia	
Total Score (0–56) = sum of score for all scales		

備註：

1. 本表摘自 <https://www.mdcalc.com/cumulative-illness-rating-scale-geriatric-cirs-g>
2. CIRS-G is a valid instrument in younger and elderly patients (Fortin M, et al, 2005.; Hudon C, et al. 2005)