

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Pembrolizumab (KEYTRUDA®)

MSD Sharp & Dohme GmbH

Modul 4 A

*Behandlung von Tumoren mit MSI-H oder mit einer dMMR
bei Erwachsenen: Nicht resezierbares oder metastasierendes
Kolorektalkarzinom*

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Inhaltsverzeichnis

	Seite
Inhaltsverzeichnis	1
Tabellenverzeichnis	2
Anhang 4-G: Weitere Ergebnisse	3
Anhang 4-G1: Definition der Immunvermittelten unerwünschten Ereignisse (AEOSI) anhand der zugeordneten PT	4

Tabellenverzeichnis

Seite

Tabelle 4 G-1: Definition der Immunvermittelten unerwünschten Ereignisse (AEOSI) anhand der zugeordneten PT in der Studie KEYNOTE 164.....	4
--	---

Anhang 4-G: Weitere Ergebnisse

Anhang 4-G1: Definition der Immunvermittelten unerwünschten Ereignisse (AEOSI) anhand der zugeordneten PT

Tabelle 4 G-1: Definition der Immunvermittelten unerwünschten Ereignisse (AEOSI) anhand der zugeordneten PT in der Studie KEYNOTE 164

AEOSI	Preferred Terms	Immune-mediated (Yes/No)
Pneumonitis	Acute interstitial pneumonitis Autoimmune lung disease Interstitial lung disease Pneumonitis Idiopathic pneumonia syndrome Organising pneumonia Immune-mediated pneumonitis	Yes
Colitis	Colitis Colitis microscopic Enterocolitis Enterocolitis haemorrhagic Necrotising colitis Colitis erosive Autoimmune colitis Immune-mediated enterocolitis	Yes
Hepatitis	Hepatitis Immune-mediated hepatitis Autoimmune hepatitis Hepatitis acute Hepatitis fulminant Drug-induced liver injury	Yes

AEOSI	Preferred Terms	Immune-mediated (Yes/No)
Nephritis	Nephritis Autoimmune nephritis Chronic autoimmune glomerulonephritis Fibrillary glomerulonephritis Focal segmental glomerulosclerosis Glomerulonephritis Glomerulonephritis acute Glomerulonephritis membranoproliferative Glomerulonephritis membranous Glomerulonephritis minimal lesion Glomerulonephritis proliferative Glomerulonephritis rapidly progressive Mesangioproliferative glomerulonephritis Nephritis haemorrhagic Tubulointerstitial nephritis Nephrotic syndrome Immune-mediated nephritis	Yes
Adrenal Insufficiency	Adrenal insufficiency Adrenocortical insufficiency acute Secondary adrenocortical insufficiency Primary adrenal insufficiency Addison's disease	Yes
Hypophysitis	Hypophysitis Hypopituitarism Lymphocytic hypophysitis	Yes
Hyperthyroidism	Hyperthyroidism Basedow's disease Thyrotoxic crisis Immune-mediated hyperthyroidism Hypothyroidism Hypothyroidic goitre Myxoedema Myxoedema coma Primary hypothyroidism Autoimmune hypothyroidism Immune-mediated hypothyroidism	Yes

AEOSI	Preferred Terms	Immune-mediated (Yes/No)
Thyroiditis	Thyroid disorder Thyroiditis Autoimmune thyroiditis Thyroiditis acute Silent thyroiditis Autoimmune thyroid disorder Immune-mediated thyroiditis	Yes
Type 1 Diabetes Mellitus	Diabetic ketoacidosis Diabetic ketoacidotic hyperglycaemic coma Fulminant type 1 diabetes mellitus Latent autoimmune diabetes in adults Type 1 diabetes mellitus Euglycaemic diabetic ketoacidosis Diabetic ketosis Ketosis-prone diabetes mellitus	Yes
Severe Skin Reactions Including Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) or Severe Skin Reactions (CTCAE-Grade 3-5)	Dermatitis bullous Dermatitis exfoliative Dermatitis exfoliative generalised Epidermal necrosis Erythema multiforme Exfoliative rash Pemphigoid Pemphigus Skin necrosis Stevens-Johnson syndrome Toxic epidermal necrolysis Toxic skin eruption SJS-TEN overlap Rash Rash erythematous Rash maculo-papular Rash pruritic Rash pustular Pruritus Pruritus genital Lichen planus Oral lichen planus Cutaneous vasculitis Vasculitic rash	Yes

AEOSI	Preferred Terms	Immune-mediated (Yes/No)
Uveitis	Iritis Uveitis Cyclitis Autoimmune uveitis Iridocyclitis Vogt-Koyanagi-Harada disease Chorioretinitis Choroiditis Immune-mediated uveitis	Yes
Pancreatitis	Pancreatitis Autoimmune pancreatitis Pancreatitis acute Pancreatitis haemorrhagic Pancreatitis necrotising Immune-mediated pancreatitis	Yes
Myositis	Myositis Necrotising myositis Polymyositis Immune-mediated myositis Rhabdomyolysis Myopathy Dermatomyositis Autoimmune myositis	Yes
Guillain-Barre Syndrome	Demyelinating polyneuropathy Guillain-Barre syndrome Axonal neuropathy Multifocal motor neuropathy Polyneuropathy idiopathic progressive Miller Fisher syndrome Subacute inflammatory demyelinating polyneuropathy	Yes
Myocarditis	Myocarditis Autoimmune myocarditis Hypersensitivity myocarditis Immune-mediated myocarditis	Yes
Encephalitis	Encephalitis Encephalitis autoimmune Limbic encephalitis Noninfective encephalitis Immune-mediated encephalitis	Yes

AEOSI	Preferred Terms	Immune-mediated (Yes/No)
Sarcoidosis	Sarcoidosis Cutaneous sarcoidosis Ocular sarcoidosis Pulmonary sarcoidosis	Yes
Infusion Reactions	Hypersensitivity Drug hypersensitivity Anaphylactic reaction Anaphylactoid reaction Cytokine release syndrome Serum sickness Serum sickness-like reaction Infusion related reaction Infusion related hypersensitivity reaction	No
Myasthenic Syndrome	Myasthenic syndrome Myasthenia gravis Myasthenia gravis crisis Ocular myasthenia	Yes
Myelitis	Myelitis Myelitis transverse	Yes

AEOSI	Preferred Terms	Immune-mediated (Yes/No)
Vasculitis	Anti-neutrophil cytoplasmic antibody positive vasculitis Aortitis Arteritis Arteritis coronary Behcet's syndrome Central nervous system vasculitis Cerebral arteritis Diffuse vasculitis Eosinophilic granulomatosis with polyangiitis Granulomatosis with polyangiitis Haemorrhagic vasculitis Hypersensitivity vasculitis Microscopic polyangiitis Ocular vasculitis Polyarteritis nodosa Pulmonary vasculitis Renal arteritis Renal vasculitis Retinal vasculitis Takayasu's arteritis Giant cell arteritis Vasculitis Vasculitis gastrointestinal Vasculitis necrotising	Yes
Cholangitis Sclerosing	Cholangitis sclerosing Autoimmune cholangitis Immune-mediated cholangitis	Yes