

ALLEGATO 5

FARMACI CON USO CONSOLIDATO NEL TRATTAMENTO CORRELATO AI TRAPIANTI PER INDICAZIONI ANCHE DIFFERENTI DA QUELLE PREVISTE DAL PROVVEDIMENTO DI AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

Per ciascun principio attivo sono riportate le indicazioni già autorizzate e le estensioni di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura

BASILIXIMAB

Indicazioni già autorizzate:

• Indicato per la profilassi del rigetto acuto in pazienti adulti e pediatrici sottoposti a trapianto renale allogenico de novo. Deve essere usato in associazione ad un trattamento immunosoppressivo a base di ciclosporina in microemulsione e corticosteroidi nei pazienti con una quantità di anticorpi reattivi inferiore all'80%, o in uno schema terapeutico immunosoppressivo di mantenimento in triplice terapia comprendente ciclosporina in microemulsione, corticosteroidi e azatioprina o micofenolato mofetile.

Estensione delle indicazioni:

• Profilassi del rigetto acuto in pazienti adulti e pediatrici sottoposti a trapianto di fegato e a Trapianto isole di Langerhans.
• Profilassi del rigetto acuto in pazienti adulti sottoposti a trapianto di rene e pancreas¹⁻¹⁸.

Everolimus

Indicazioni già autorizzate:

• Profilassi del rigetto d'organo in pazienti adulti, a rischio immunologico da lieve a moderato, sottoposti a trapianto renale o cardiaco allogenico. Certican deve essere utilizzato in associazione con ciclosporina in microemulsione e corticosteroidi.

Estensione delle indicazioni:

• Profilassi del rigetto acuto in pazienti pediatrici sottoposti a trapianto di rene.
• Profilassi del rigetto acuto in pazienti adulti sottoposti a trapianto di polmone.
• Profilassi del rigetto acuto in pazienti adulti sottoposti a trapianto di fegato.
• Pazienti con trapianto di fegato che necessitano la riduzione/sospensione nell'inibitore della calcineurina con problemi di tossicità renale¹⁹⁻²⁸.
• Trapianto di fegato pediatrico²⁹.

Fattori di crescita dei leucociti(filgrastim, lenograstim)

Indicazioni già autorizzate:

• Trattamento della neutropenia

Estensione delle indicazioni:

• Neutropenia (neutrofili < 750/L) nei pazienti trapiantati di fegato o con diagnosi clinica di cirrosi, che ricevono interferone standard o pe-

ghilato in monoterapia o in combinazione con ribavirina e che presentano risposta virologica precoce alla terapia³⁰⁻³⁷.

Immunoglobulina di coniglio antitimocitaria

Indicazioni già autorizzate:

• Profilassi nell'adulto della malattia acuta e cronica da trapianto verso ospite in trapianti da donatore familiare non immunocompatibile o immunocompatibile non familiare (*Graft versus Host Disease, GvHD*).

Estensione delle indicazioni:

• Trattamento nell'adulto della malattia acuta e cronica da trapianto verso ospite (*Graft versus Host Disease, GvHD*).
• Profilassi e trattamento nel paziente pediatrico della malattia acuta e cronica da trapianto verso ospite (*Graft versus Host Disease, GvHD*).
• Regime di condizionamento nel trapianto autologo per malattie autoimmuni³⁸⁻⁴⁴.

Micofenolato Mofetile

Indicazioni già autorizzate:

• Trapianto rene; trapianto rene pediatrico; trapianto cuore; trapianto fegato.

Estensione delle indicazioni:

• Trapianto cuore pediatrico; trapianto fegato pediatrico; trapianto pancreas; trapianto polmone; trapianto di midollo osseo; trapianto isole di Langerhans.
• Trapianto di cuore pediatrico⁴⁵⁻⁵³.
• Trapianto di fegato pediatrico⁵⁴⁻⁶⁴.
• Trapianto di pancreas⁶⁵⁻⁷⁶.
• Trapianto di polmone⁷⁷⁻⁸⁶.
• Trapianto di isole di Langerhans⁸⁷⁻⁸⁸.

Micofenolato Sodico

Indicazioni già autorizzate:

• Myfortic è indicato in associazione con ciclosporina e corticosteroidi, per la profilassi del rigetto acuto, in pazienti adulti che ricevono un trapianto allogenico di rene.

Estensione delle indicazioni:

• Profilassi del rigetto acuto in pazienti adulti con trapianto di cuore. Pazienti adulti con trapianto di fegato e di cuore in cui il micofenolato mofetile dia effetti collaterali di tipo gastroenterico che richiedano la diminuzione/sospensione della dose⁸⁹⁻⁹⁵.
• Profilassi del rigetto acuto nel trapianto di rene in associazione con Tacrolimus.
• Trapianto di rene⁹⁶⁻⁹⁸.

RAPAMICINA

Indicazioni già autorizzate:

• Trapianto rene.

Estensione delle indicazioni:

• Trapianto fegato; trapianto pediatrico di fegato e/o rene; trapianto midollo; trapianto pancreas, cuore, polmone.
• Trapianto isole di Langerhans.

- Trapianto di fegato⁹⁹⁻¹¹⁴.
- Trapianti pediatrici di rene e fegato¹¹²⁻¹¹⁵.
- Trapianti di midollo¹¹⁶⁻¹¹⁸.
- Trapianto di pancreas, cuore, polmone¹¹⁹⁻¹²⁵.
- Trapianto di isole di Langerhans¹²⁶⁻¹²⁸.

TACROLIMUS

Indicazioni già autorizzate:

- Profilassi AR e trattamento AR in: trapianto rene, trapianto fegato, trapianto cuore; trattamento AR in: trapianto rene-pancreas, trapianto pancreas, trapianto cuore-polmone, trapianto polmone, trapianto intestino multi viscerale.

Estensione delle indicazioni:

- Profilassi AR in trapianto di cuore-polmone, trapianto polmone, trapianto pancreas, trapianto rene - pancreas, trapianto intestino trapianto isole di Langerhans; profilassi AR e trattamento GVHD in trapianto midollo osseo.
- Profilassi Tx polmone¹²⁹⁻¹³¹.
- Profilassi Tx Rene pancreas e pancreas¹³²⁻¹³⁴.
- Profilassi Tx Intestino-Multiviscerale¹³⁵.
- Trapianto di Midollo¹³⁶⁻¹⁴⁰.
- Trapianto di isole di Langerhans^{126,127}.
- Tutte le indicazioni anche in associazione con altri farmaci ad attività immunosoppressiva o immunomodulante e/o steroide¹⁴¹⁻¹⁶⁵.

THYMOGLOBULINE ATC: L04AA04

Indicazioni già autorizzate:

- Profilassi nell'adulto della malattia acuta e cronica da trapianto verso ospite (Graft vs Host Disease) nel trapianto da donatore familiare non immunocompatibile o immunocompatibile non familiare.

Estensione delle indicazioni:

- Profilassi nell'adulto della malattia acuta e cronica da trapianto verso ospite (GvHD) nel trapianto da donatore familiare immunocompatibile (HLA identico)¹⁶⁶⁻¹⁷⁰.

VALGANCICLOVIR

Indicazioni già autorizzate:

- Prevenzione della malattia da CMV in pazienti CMV negativi e sottoposti a trapianto d'organo SOLIDO da donatore CMV positivo. trattamento di induzione e mantenimento della retinite da CMV in pazienti con AIDS.

Estensione delle indicazioni:

- Trapianto midollo osseo; trapianto d'organo solido pediatrico¹⁷⁴⁻¹⁷⁸.
- Infezione da Citomegalovirus in pazienti pediatrici con trapianto¹⁷⁹⁻¹⁸³.

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