

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

Nome composto	Indicazioni già autorizzate	Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.
Basiliximab	Indicato per la profilassi del rigetto acuto in pazienti adulti e pediatrici sottoposti a trapianto renale allogenico <i>de novo</i> . 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.	<p>Profilassi del rigetto acuto in pazienti adulti e pediatrici sottoposti a trapianto di fegato e a Trapianto isole di Langerhans.</p> <p>Profilassi del rigetto acuto in pazienti adulti sottoposti a trapianto di rene e pancreas</p> <p>M. Spada et al. Randomized Trial of Basiliximab Induction versus steroid Therapy in Pediatric Liver Allograft Recipients Under Tacrolimus Immunosuppression Am. J. Transplantation 2006; 6: 1913-1921 S. Gruttadauria et al. A Safe Immunosuppressive Protocol in Adult to-Adult Living Related Liver Transplantation. Transplant Proc 38, 1106-1108 (2006) Laura Lladò et al. Immunosuppression without steroids in liver transplantation is safe and reduces infection and metabolic complications: Results from a prospective multicenter randomized study. J. Hepatol 44 / (2006) 710-718 D.W. Orr et al. Anti-Interleukin 2 Receptor Antibodies and Mycorphenolate Mofetil for Treatment of Steroid - Resistant Rejection in Adult Liver Transplantation. Transplant Proc 37, 4373-4379 (2005) R. Ganschow et al. Long.-tern results of basiliximab induction immunosuppression in paediatric liver transplants recipients. Pediatr Transplantation 2005; 9: 741-745 M. Spada et al. An anti-interleukin 2 receptor monoclonal antibody to reduce the incidence of acute cellular rejection afetr liver transplantation. Pediatr Transplantation 2000, Vol 4., p. 62 (Abs P49) R. Ganschow et al. The anti-interleukin 2 receptor antodoby basiliximavb after pediatric liver transplantation: a pilot study. Pediatr Transplantation 2000, Vol. 4, p. 95 (Abs O145) R: Ganschow et al. First experience with basiliximab in pediatric liver graft recipients. Pediatr Transplantation 2001, Vol. 5, p. 353-358 F. Filippini et al. Study of Simulect.Based, Steroid-Free Immunosuppressive Regimen in HCV+ De Novo Liver Transplant Patients: Preliminary Results. Transplantation Proceedings 33, 3211-3212 (2001) D.A. Kelly The use of anti-interleukin 2 receptor antibodies in pediatric liver transplantation. Pediatr Transplantation 2001; 5: 386-389 P. Neuhaus et al. Improved Treatment Response With Basiliximab Immunoprophylaxis Afetr Liver Transplantation: Results from a Double-Blind Randomized Placebo-Controlled Trial. Liver Transplantation 2002, Vol. 8, 132-142 M. Cantarovich et al. Anti-CD25 Mmonoclonal antibody coverage allows for calcineurin inhibitor "Holiday" in solid organ transplant patients with acute renal dysfunction. Transplantation Vol 73 n 7 B. Nashed. The Interleukin " "Pathway" and the Route to Logical Immunosuppression. Current Issues in Liver and Small Bowel Transplantation 2002, 9, 164-174 E. Kuse et al. Immunoprophylaxis with Simulect ® (Basiliximab) in combination with Cyclosporine and Steoids in Liver Transplantation. American Journal of Transplantation 2001, vol 1, p 202 (Abs 266) A. Venze et al. Basiliximab monotherapy following B-cell lymphoma after pediatric liver transplantation and anti-</p>

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		<p>CD20 therapy. <i>Pediatr Transplantation</i> 2003; 7: 404-407 R. Reding et al. Stepirid-free liver transplantation in children. <i>Lancet</i> 2003; 362: 2068-70 C.L. Liu et al. Interleukin 2-Receptor Antibody (Basiliximab) for Immunosuppressive Induction Therapy After Liver Transplantation: A Protocol With Early Elimination of Seroids and Reduction of Tacrolimus Dosage. <i>Liver Transplantation</i>, 10: No. 6 (June) 728-733 S. Grattadauria et al. Basiliximab in a Triple-Drug Regimen with Tacrolimus and Steroids in Liver Transplantation. <i>Transplantation Proceedings</i>, 37, 2611-2613 (2005)</p> <p>Trapianto di isole di Langerhans Oberholzer J, Toso C, Triponez F, Ris F, Bucher P, et al: Human islet allotransplantation with Basiliximab in type I diabetic patients with end-stage renal failure. <i>Transplantation Proceedings</i>, 34, (3) 823-825</p> <p>Trapianto di Rene-Pancreas Zhang R, Florman S, Devidoss S, Zarifian A, Yau CL, Paramesh A, Killackey M, Alper B, Fonseca V, Slakey D. A comparison of long-term survivals of simultaneous pancreas-kidney transplant between African American and Caucasian recipients with basiliximab induction therapy. <i>Am J Transplant</i>. 2007 Jul;7(7):1815-21.</p> <p>Boggi U, Vistoli F, Del Chiaro M, Signori S, Amorese G, Vahadia Bartolo T, Sgambelluri F, Barsotti M, Tregnaghi C, Paleologo G, Coppelli A, Giannarelli R, Rizzo G, Marchetti P, Mosca F. Neoral versus prograf in simultaneous pancreas-kidney transplantation with portal venous drainage: three-year results of a single-center, open-label, prospective, randomized pilot study. <i>Transplant Proc</i>. 2005 Jul-Aug;37(6):2641-3.</p> <p>Chow FY, Polkinghorne K, Saunder A, Kerr PG, Atkins RC, Chadban SJ. Historical controlled trial of OKT3 versus basiliximab induction therapy in simultaneous pancreas-renal transplantation. <i>Nephrology (Carlton)</i>. 2003 Aug;8(4):212-6.</p> <p>Profilassi del rigetto acuto in pazienti adulti e pediatrici sottoposti a trapianto di cuore.</p> <p>Trapianto di cuore J. Segovia et al A randomized Multicenter Comparison of Basiliximab and Muromonab (OKT3) in Heart Transplantation: SIMCOR Study . <i>Transplantation</i> 2006; 81:1542-1548</p> <p>F.M. Mattei et al. Lower Risk of Infectious Deaths in Cardiac Transplant Patients Receiving Basiliximab versus Anti-thymocyte Globulin as Induction Therapy <i>J Heart Lung Transplantation</i> 2007; 26:693-9</p> <p>Katrina A. Ford et al. Initial Data on Basiliximab in Critically Children Undergoing Heart Transplantation <i>J Heart Lung Transplantation</i> 2005; 24:1284-88</p>

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		<p>K.M. Ward et al. Basiliximab in pediatric heart transplantation-Initial Experience J Heart Lung Transplantation 2004; Abs 103 – Vol 23 – Number 2S</p>
Everolimus	<p>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.</p>	<p>Profilassi del rigetto acuto in pazienti pediatriche 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 renale.</p> <p>L.Pape et al. Reversal of loss of glomerular fuiltration rate in children with transplant nephropathy after switch to everolimus and low-dose cyclosporine A. <i>Pediatr Transplantation</i> 2007; 11: 291-293 Vester U et al. Everolimus (Certican) in combination with Neoral in Pediatric Renal Transplant Recipients: Interim analysis after 3 Months. <i>Transplantattion Proceedings</i>, 34, 2209-2210 (2002) P. Hoyer et al. Everolimus in Pediatric de Novo Renal Transplant Patients. <i>Transplantation</i> Vol 75; 2082-2085 (2003) R. Van Damme-Lombaerts et al. Single-dose pharmacokinetics and tolerability of everolimus in stable pediatric renal transplant patients. <i>Pediatric Transplantation</i> 2002; 6: 147-152 J.M. Kovarik et al. Everolimus in Pulmonary Transplantation: Pharmacokinetics and Exposure-Response Relationship. <i>The Journal of Heart and Lung Transplantation</i> Vol. 25 No 4 (2006) Everolimus versus Azathioprine in Maintenance Lung Transplant Recipients: An International, Randomized Double-Blind Clinical Trial. <i>American Journal of Transplantation</i> 2006; 6: 169-177 Azzola et al. Everolimus and Mycophenolate Mofetil are poten inhibitors of fibroblast proliferation after lung Transplantation. <i>Transplantation</i> Vol 77, No. 4 (2004) G. Everson. Everolimus and mTOR Inhibitors in Liver Transplantation: Opening the "Box". <i>Liver Transplantation</i> 12: 1571-1573, 2006 C.D. Poirier Promise of Neoral C2; Basiliximab and Everolumus in Lung Transplantation. <i>Transplantation Proceedings</i>, 36 (Suppl 2S)N, 509S-513S (2004) Levy e al. Safety, Telerability and Efficacy of Everolimus in De Novo Liver Transplant Recipients: 12-and 36-Month Results. <i>Liver Transplantation</i> 12: 1640-1648, 2006</p> <p>Trapianto di fegato pediatrico</p> <p>Trapianto di fegato Katrina A. Ford Paediatric Immunosuppression Following Solid Organ Transplantation <i>Arch Dis Child Educ Ed</i> 2006; 91:87-91</p>

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<p>Fattori di crescita dei leucociti:</p> <ul style="list-style-type: none"> • filgrastim • lenograstim 	<p>Trattamento della neutropenia</p>	<p>Neutropenia (neutrofili < 750/L) nei pazienti trapiantati di fegato o con diagnosi clinica di cirrosi, che ricevono interferone standard o peghilato in monoterapia o in combinazione con ribavirina e che presentano risposta virologica precoce alla terapia.</p> <p>Manns MP, et al. and the International Hepatitis Interventional Therapy Group. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. <i>Lancet</i> 2001;358:958-65.</p> <p>Fried MW, et al. Peg Interferon alf 2a plus Ribavirin in chronic hepatitis C virus infection. <i>N Engl J Med</i> 2002; 347: 975-82.</p> <p>Higashi Y, et al. Case report: agranulocytosis induced by inteferon alpha therapy for chronic hepatitis C <i>J Gastroenterol Hepatol</i> 1996; 11:1012-1015.</p> <p>Van Thiel DH, et al. Combination treatment of advanced HCV associated liver disease with interferon and G-CSF. <i>Hepatology</i> 1995; 42:907-12</p> <p>Fukuda A, et al. Effects of interferon alpha on peripheral neutrophil counts and serum granulocyte colony-stimulating factor for the treatment of chronic hepatitis C <i>Cell Mol Ther</i> 2000; 6:149-154.</p> <p>Carreno V, et al. Randomized controlled trial of recombinant human granulocyte-macrophage colony-stimulating factor for the treatment of chronic hepatitis C <i>Cytokine</i> 2000; 12: 165-70.</p> <p>Shiffman ML, et al. Use of granulocyte macrophage colony stimulating factor alone or in combination with interferon-alpha-2b for treatment of chronic hepatitis C <i>J Hepatol</i> 1998; 28: 382-89.</p> <p>National Institutes of health consensus development conference statement: Management of hepatitis C: 2002 – June 10-12 2002. <i>Hepatology</i> 2002; 36: S3-S20.</p>
<p>Immunoglobulina di coniglio antitimocitaria</p>	<p>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)</p>	<p>Trattamento nell'adulto della malattia acuta e cronica da trapianto verso ospite (Graft versus Host Disease, GvHD)</p> <p>Profilassi e trattamento nel paziente pediatrico della malattia acuta e cronica da trapianto verso ospite (Graft versus Host Disease, GvHD)</p> <p>Regime di condizionamento nel trapianto autologo per malattie autoimmuni</p> <p>Use of antithymocyte globulin for treatment of steroid-refractory acute graft-versus-host disease: an international practice survey B Hsu, R May, G Carrum, R Krance and D Przepioraka <i>Bone Marrow Transplantation</i> (2001) 28, 945-950</p> <p>Treatment of acute graft-versus-host disease with low-dose, alternate-day antithymocyte globulin Francesco Graziani, Maria Teresa Van Lint, Alida Dominiotto, Anna Maria Raiola, Carmela Di Grazia, Teresa Lamparelli, Francesca Gualandi, Stefania Bregante, Merilù Fiorone, Barbara Bruno, Andrea Bacigalupo</p>

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		<p>haematologica 2002; 87:973-978 Fludarabine, cyclophosphamide and anti-thymocyte globulin for alternative donor transplants in acquired severe aplastic anemia: a report from the EBMT-SAA Working Party A Bacigalupo, F Locatelli, E Lanino, J Marsh, G Socie`, S Maury, A Prete, A Locasciulli, S Cesaro and J Passweg, for the Severe Aplastic Anemia Working Party of the European Group for Blood and Marrow Transplantation (SAA WP-EBMT) Bone Marrow Transplantation (2005) 36, 947-950 Fludarabine, cyclophosphamide plus thymoglobulin conditioning regimen for unrelated bone marrow transplantation in severe aplastic anemia HJ Kang, HY Shin, HS Choi and HS Ahn Bone Marrow Transplantation (2004) 34, 939-943 Reduced intensity conditioning using intravenous busulfan, fludarabine and rabbit ATG for children with nonmalignant disorders and CML B Horn, L-A Baxter-Lowe, L Englert, A McMillan, M Quinn, K DeSantes and M Cowan Bone Marrow Transplantation (2006) 37, 263-269 Nonmyeloablative stem cell transplantation for nonmalignant diseases in children with severe organ dysfunction A Kikuta, M Ito, K Mochizuki, M Akaihata, K Nemoto, H Sano and H Ohto Bone Marrow Transplantation (2006) 38, 665-669 Use of antithymocyte globulin for treatment of steroid-refractory acute graft-versus-host disease: an international practice survey B Hsu, R May, G Carrum, R Krance and D Przepiora Bone Marrow Transplantation (2001) 28, 945-950 Favourable response to antithymocyte globulin therapy in resistant acute graft-versus-host disease A. Tagliabue, P. Corti, E Vigano`, S. Bonanomi, C. Uderzo Bone Marrow Transplantation (2005) 36, 45</p>
Micofenolato Mofetile	Trapianto rene; trapianto rene pediatrico; trapianto cuore; trapianto fegato	Trapianto cuore pediatrico; trapianto fegato pediatrico; trapianto pancreas; trapianto polmone; trapianto di midollo osseo; trapianto isole di Langerhans Trapianto di cuore pediatrico J. Agüero et al. Influence of Immunosuppression Regimen on Heart Transplantation Survival. Transplantation Proceedings 2006; 38: 2550-2 Olivia Boyer et al. Improvement of Renal Function in Pediatric Heart Transplant Recipients Treated with Low-Dose Calcineurin Inhibitor and Mycophenolate Mofetil. Transplantation 2005; 79 (10): 1405-1410 Dipchand AI et al. Mycophenolate mofetil in pediatric heart transplant recipients: A single-center experience. Pediatr Transplantation 2001; 5: 112-118 Tonshoff B et al. Treatment strategies in pediatric solid organ transplant recipients with calcineurin inhibitor-induced nephrotoxicity. Pediatr Transplantation 2006; 10: 721-729 Groetzner J et al. Cardiac transplantation in pediatric patients: fifteen-year experience of a single center. Ann Thorac Surg 2005; 79 (1): 53-60 <i>Since the introduction of mycophenolate mofetil, freedom from acute rejection increased to 62%.</i> Gajarski RJ et al. Lack of correlation between MMF dose and MPA level in pediatric and young adult cardiac transplant patients: does the MPA level matter? Am J Transplant 2004; 4 (9): 1495-500 Shaddy RE et al. Mycophenolic mofetil reduces the HLA antibody response of children to valved allograft implantation. Ann-Thorac-Surg 2004; 77 (5): 1734-9 <i>This study demonstrates the ability to pharmacologically abrogate the HLA class I antibody response to valved allograft implantation in children using MMF.</i> Boucek RJ, Boucek MM Pediatric heart transplantation. Curr-Opin-Pediatr 2002; 14 (5): 611-9

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		<p><i>Currently, recipients are maintained on immunosuppressive medications that target calcineurin (eg, cyclosporine, tacrolimus), lymphocyte proliferation (eg, azathioprine, mycophenolate mofetil (MMF), sirolimus) and, in some instances antiinflammatory corticosteroids.</i></p> <p>Kobashigawa Review of Major Clinical Trials with Mycophenolate Mofetil in Cardiac Transplantation. <i>Transplantation</i> 2005; 80 (2S): S235–S243</p> <p>Trapianto di Fegato pediatrico Renz JF et al. Mycophenolate mofetil, microemulsion cyclosporine, and prednisone as primary immunosuppression for pediatric liver transplant recipients. <i>Liver Transpl Surg</i>. 19995(2): 136-43 Chardot C et al. Use of mycophenolate mofetil as rescue therapy after pediatric liver transplantation. <i>Transplantation</i> 2001; 71 (2): 224-9 <i>These preliminary results suggest that MMF is an effective and safe immunosuppressant in pediatric LT recipients. Its use is hampered by frequent gastrointestinal and hematological side-effects. MMF does not seem to increase the risk of PTLN nor CMV disease.</i> Aw MM et al. Calcineurin-inhibitor related nephrotoxicity- reversibility in paediatric liver transplant recipients. <i>Transplantation</i> 2001; 72 (4): 746-9 <i>MMF allows the recovery of renal function from CI related nephrotoxicity in more than 70% of paediatric liver transplant recipients with renal impairment.</i> Ferraris JR et al. Mycophenolate mofetil and reduced doses of cyclosporine in pediatric liver transplantation with chronic renal dysfunction: changes in the immune responses. <i>Pediatr Transplant</i> 2004; 8 (5): 454. Evans HM et al. Mycophenolate Mofetil for Renal Dysfunction after Pediatric Liver Transplantation. <i>Transplantation</i> 2005; 79: 1575–1580) Klupp J et al. Indications of Mycophenolate Mofetil in Liver Transplantation. <i>Transplantation</i> 2005; 80: S142–S146 Marion M. Mycophenolic Acid Pharmacokinetics in Pediatric Liver Transplant Recipients. <i>Liver Transplantation</i> 2003; 9 (4): 383-388 Apezato ML et al. Mycophenolate mofetil promotes prolonged improvement of renal dysfunction after pediatric liver transplantation: Experience of a single center. <i>Pediatr Transplantation</i> 2007; 11: 82–86. Tredger JM. Monitoring Mycophenolate in Liver Transplant Recipients: Toward a Therapeutic Range. <i>Liver Transplantation</i> 2004; 10 (4): 492–502 Mention K et al. Renal function outcome in pediatric liver transplant recipients. <i>Pediatr-Transplant</i> 2005; 9 (2): 201-7 Nobili V et al. Mycophenolate mofetil in pediatric liver transplant patients with renal dysfunction: preliminary data. <i>Pediatr-Transplant</i> 2003; 7 (6): 454-7</p> <p>Trapianto di Pancreas Odorico JS et al. Improved solitary pancreas transplant graft survival in the modern immunosuppressive era. <i>Cell-Transplant</i> 2000; 9 (6): 919-27 Rigotti P et al. Mycophenolate mofetil (MMF) versus azathioprine (AZA) in pancreas transplantation: a single-center experience. <i>Clin-Nephrol</i> 2000; 53 (4): 52-4 <i>In conclusion, patients treated with MMF required less frequent and less intensive treatment for acute rejection. However, its short- and long-term side effects should be further investigated.</i> Gruessner RW et al. Mycophenolate mofetil in pancreas transplantation. <i>Transplantation</i> 1998; 66 (3): 318-23 <i>For SPK recipients, the incidence of acute reversible rejection episodes was significantly lower with MMF than with azathioprine.</i> Paleologo G et al. Solitary pancreas transplantation: preliminary findings about early reduction of proteinuria in incipient or evident diabetic type I nephropathy. <i>Transplant Proc</i> 2004; 36 (3): 591-6 <i>The immunosuppressive therapy used basilixmab induction and tacrolimus, mycophenolate mofetil (MMF), and low dose steroid maintenance therapy.</i></p>

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		<p>Kaufman DB et al. Pancreas transplantation at Northwestern University. Clin Transpl 2000; 239-46 <i>We have found that multimodal immunotherapy including induction with tacrolimus-based maintenance combined with either MMF or sirolimus, with or without corticosteroids, resulted in excellent patient and graft survival rates with low rates of rejection.</i></p> <p>Sutherland DE et al. Lessons learned from more than 1,000 pancreas transplants at a single institution. Ann Surg 2001; 233 (4): 463-501 <i>From December 16, 1966, to March 31, 2000, the authors performed 1,194 pancreas transplants. The analyses were divided into five eras: era 0, 1966 to 1973 (n = 14), historical; era 1, 1978 to 1986 (n = 148), transition to cyclosporine for immunosuppression, multiple duct management techniques, and only solitary (PAK and PTA) transplants; era 2, 1986 to 1994 (n = 461), all categories (SPK, PAK, and PTA), predominantly bladder drainage for graft duct management, and primarily triple therapy (cyclosporine, azathioprine, and prednisone) for maintenance immunosuppression; era 3, 1994 to 1998 (n = 286), tacrolimus and mycophenolate mofetil used; and era 4, 1998 to 2000 (n = 275), use of daclizumab for induction immunosuppression, primarily enteric drainage for SPK transplants, pretransplant immunosuppression in candidates awaiting PTA Patient and graft survival rates have significantly improved over time as surgical techniques and immunosuppressive protocols have evolved.</i></p> <p>Jordan ML et al. Steroid withdrawal for pancreas transplants under tacrolimus immunosuppression. Transplant-Proc 2001; 33 (1-2): 1655</p> <p>Egidi FM. Management of Hyperglycaemia After Pancreas Transplantation. Are New Immunosuppressants the Answer? Drugs 2005; 65 (2): 153-166</p> <p>Garcia VD et al. Immunosuppression in Pancreas Transplantation: Mycophenolate Mofetil Versus Sirolimus. Transplantation Proceedings 2004; 36: 975-977</p> <p>Gruessner AC, Sutherland DER. Pancreas transplant outcomes for United States (US) and non-US cases as reported to the United Network for Organ Sharing (UNOS) and the International Pancreas Transplant Registry (IPTR) as of June 2004. Clin Transplant 2005; 19: 433-455.</p> <p>Jung M et al. Comparison of Azathioprine and Mycophenolate Mofetil for the Prevention of Acute Rejection in Recipients of Pancreas Transplantation. J Clin Pharmacol 2001;41: 861-869. <i>In conclusion, compared with AZA, MMF significantly reduces the rate of biopsy-proven pancreas rejection during the first 6 months of transplantation and is well tolerated.</i></p> <p>Mark W et al. Impact of Steroid Withdrawal on Metabolic Parameters in a Series of 112 Enteric/Systemic-Drained Pancreatic Transplants. Transplantation Proceedings 2005, 37, 1821-1825</p> <p>Trapianto di Polmone</p> <p>Izbicki G et al. Improved Survival After Lung Transplantation in Patients Treated With Tacrolimus/Mycophenolate Mofetil as Compared With Cyclosporine/Azathioprine. Transplantation Proceedings 2002; 34: 3258-3259</p> <p>Lama R et al. Lung Transplants With Tacrolimus and Mycophenolate Mofetil: A Review. Transplantation Proceedings 2003; 35: 1968-1973</p> <p>Palmer SM et al. Results of a randomized, prospectiv, multicenter trial of Mycophenolate Mofetil versus azathioprine in the prevention of acute lung allograft rejection. Transplantation 2001; 71: 1772-1776</p> <p>McNeil K et al. Comparison of Mycophenolate Mofetil and Azathioprine for Prevention of Bronchiolitis Obliterans Syndrome in De Novo Lung Transplant Recipients. Transplantation 2006; 81 (7): 998-1003</p> <p>Roman A et al. Preliminary Results of Rescue Therapy With Tacrolimus and Mycophenolate Mofetil in Lung Transplanted Patients With Bronchiolitis Obliterans. Transplantation Proceedings 2002; 34: 146-147</p> <p>Treede H et al. Tacrolimus versus Cyclosporine after Lung Transplantation: A Prospective, Open, Randomized Two-Center Trial Comparing Two Different Immunosuppressive Protocols. J Heart Lung Transplant 2001; 20: 511-517.</p> <p>Zuckermann A et al. Comparison Between Mycophenolate Mofetil and Azathioprine-Based Immunosuppressions in Clinical Lung Transplantation. J Heart Lung Transplant 1999;18: 432-440.</p> <p>Zuckermann A et al. Benefit of Mycophenolate Mofetil in Patients With Cyclosporine A-Induced Nephropathy</p>

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		<p>After Lung Transplantation. Transplantation Proceedings 1999; 31: 1160-1161 <u>Bhorade SM</u> et al. Comparison of three tacrolimus-based immunosuppressive regimens in lung transplantation. <u>Am J Transplant.</u> 2003; 3 (12): 1570-5 <i>Addition of daclizumab and MMF to a tacrolimus-based immunosuppressive regimen decreased the incidence of acute rejection episodes without increasing any adverse events in our lung transplantation population.</i> <u>Groetzner J</u> et al. Conversion to sirolimus and mycophenolate can attenuate the progression of bronchiolitis obliterans syndrome and improves renal function after lung transplantation. <u>Transplantation.</u> 2006; 81 (3): 355-60 <i>After BOS was diagnosed, conversion to MMF and Sir stabilized graft function only in some of the converted patients. Therefore, earlier administration of Sir-based immunosuppression might be a more promising approach. Whether conversion to CNI-free immunosuppression can actually ameliorate the extent or progression of BOS has to be investigated in randomized trials.</i></p> <p>Trapianto di isole di Langerhans Shapiro AMJ, Ricordi C, Hering BJ et al: International trial of the Edmonton Protocol for islet transplantation. <u>N Engl J Med</u> 2006; 355: 1318-30. Froud T, Baidal DA, Ponte G, Ferreira DV, Ricordi C, Alejandro R: Resolution of neurotoxicity and beta-cell toxicity in an islet transplant recipient following substitution of tacrolimus with MMF. <u>Cell transplant</u> 2006, 15 (7): 613-629</p>
Micofenolato Sodico	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.	<p>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 dose.</p> <p>J. Kobashigawa et al. Similar Efficacy and Safety of Enteric-coated Mycophenolate Sodium (E-MPS, Myfortic) compared with Mycophenolate Mofetil (NNF) in de Novo Transplant Recipients: Results of a 12-Month, Single-blind, Randomized, Parallel-Group, Multicenter Study. <u>The Journal of Heart and Lung Transplantation.</u> Vol. 25, Number 8, 2006 M. Zackliczynski et al. Letter: Elective conversion from CellCept to Myfortic under Control of Mycophenolate Acid Concentration in Stable Heart Transplant Recipients. <u>The Journal of Heart and Lung Transplantation,</u> Vol. 26, No. 3, 2007 Pharmacokinetics and variability of mycophenolic acid form enteric-coated mycophenolate sodium compared with mycophenolate mofetil in de novo heart transplant recipients. <u>Clin Transplant</u> 1997; 21: 18-23 J. Dumortier et al. Conversion from Mycophenolate Mofetil to Enteric-coated Mycophenolate Sodium in Liver Transplant Patients Gastrointestinal Disorders: A Pilot Study. <u>Liver Transplantation</u> 12: 1342-1346, 2006 Cantisani G.P.C. Enteric-coated Mycophenolate Sodium Experience in Liver Transplant Patients. <u>Transplantation Proceedings,</u> 38: 932-933, 2006 H.W. Sollinger. Mycophenolate in transplantation. <u>Clin Transplant</u> 2004;18: 485-492 L. Chan et al. Patient-Reported Gastrointestinal Symptom Burden and Health-Related Quality of Life following Conversion from Mycophenolate Mofetil to Enteric-Coated Mycophenolate Sodium. <u>Transplantation</u> Vol 81, No 9 2006</p> <p>Profilassi del rigetto acuto nel trapianto di rene in associazione con Tacrolimus</p>

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		<p>Trapianto di rene J.M. Puig et al. Comparison of Mycophenolate Mofetil (MMF) and enteric-coated mycophenolate sodium (EC-MPS) pharmacokinetic profile in stable renal transplant (RT) patients treated with tacrolimus (FK) without steroids American Journal of Transplantation 7: 349-349; 780 Suppl. 2 May 2007</p> <p>P. Bolin et al. Improvement in 3-Month Patient Reported Gastrointestinal Symptoms After Conversion From Mycophenolate Mofetil to Enteric-Coated Mycophenolate Sodium in Renal Transplant Patients Transplantation 2007; 84:1443-1451</p> <p>K. Budde et al. Conversion from Mycophenolate Mofetil to Enteric-Coated Mycophenolate Sodium in Maintenance Renal Transplant Recipients Receiving Tacrolimus: Clinical Pharmacokinetics, and Pharmacodynamic Outcomes Transplantation 2007;83:417-424</p>
<p>Rapamicina</p>	<p>Trapianto rene</p>	<p>Trapianto fegato; trapianto pediatrico di fegato e/o rene; trapianto midollo;trapianto pancreas, cuore, polmone. Trapianto isole di Langerhans</p> <p>Trapianto di fegato Wiesner R, Klintmalm GB, McDiarmid S, and the Rapamune Liver Transplant Study Group. SIROLIMUS IMMUNOTHERAPY RESULTS IN REDUCED RATES OF ACUTE REJECTION IN DE NOVO ORTHOTOPIC LIVER TRANSPLANT RECIPIENTS. In: American Journal of Transplantation; 2002; Washington; 2002. Maheshwari A, Torbenson MS, Thuluvath PJ. Sirolimus Monotherapy Versus Sirolimus in Combination with Steroidsand/or MMF for Immunosuppression After Liver transplantation. Dig Dis Sci 2006. Zaghla H, Selby RR, Chan LS, Kahn JA, Donovan JA, Jabbour N, et al. A comparison of sirolimus vs. calcineurin inhibitor-based immunosuppressive therapies in liver transplantation. Alimentary Pharmacology and Therapeutics 2006;23(4):513-520. Trotter JF, Wallack A, Steinberg T. Low incidence of cytomegalovirus disease in liver transplant recipients receiving sirolimus primary immunosuppression with 3-day corticosteroid taper. Transplant Infect Dis 2003;5(4):174-180. Trotter JF. Sirolimus in liver transplantation. Transplant Proc 2003;35(3 Suppl):S193-200. Neff GW, Montalbano M, Tzakis AG. Ten years of sirolimus therapy in orthotopic liver transplant recipients. Transplant Proc 2003;35(3 Suppl):S209-16. McAlister VC, Peltekian K, Gao Z, Mahalati K, Dominquez J, MacDonald AS. Liver and kidney pancreas transplantation using tacrolimus, sirolimus and steroid immunosuppression. Transplantation 1999;67(9):S601. Watson CJ, Friend PJ, Jamieson NV, Frick TW, Alexander G, Gimson AE, et al. Sirolimus: a potent new immunosuppressant for liver transplantation. Transplantation 1999;67(4):505-509. Kneteman NM, Oberholzer J, Al Saghier M, Meeberg GA, Blitz M, Ma MM, et al. Sirolimus-based immunosuppression for liver transplantation in the presence of extended criteria for hepatocellular carcinoma. Liver Transpl 2004;10(10):1301. Neff GW, Montalbano M, Slapak-Green G, Meyer D, Berney T, Safdar K, et al. Sirolimus therapy in orthotopic liver transplant recipients with calcineurin inhibitor related chronic renal insufficiency. Transplant Proc 2003;35(8):3029-3031.</p>

Nome composto	Indicazioni già autorizzate	Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.
		<p>Nair S, Eason J, Loss G. Sirolimus monotherapy in nephrotoxicity due to calcineurin inhibitors in liver transplant recipients. <i>Liver Transpl</i> 2003;9(2):126-9.</p> <p>Nour B, Egidi MF, Cowan PA, Sebastian A, Shokouh-Amiri MH, Vera SH, et al. Safety and effectiveness of conversion to sirolimus in liver transplant recipients with renal dysfunction. in: <i>American Journal of Transplantation</i>; 2002; 2002.</p> <p>Sanchez EQ, Martin AP, Ikegami T, Uemura T, Narasimhan G, Goldstein RM, et al. Sirolimus conversion after liver transplantation: improvement in measured glomerular filtration rate after 2 years. <i>Transplant Proc</i> 2005;37(10):4416-23.</p> <p>Sindhi R, Seward J, Mazariegos G, Soltys K, Seward L, Smith A, et al. Replacing calcineurin inhibitors with mTOR inhibitors in children. <i>Pediatric Transplantation</i> 2005;9(3):391-397.</p> <p>Vester U, Kranz B, Nadalin S, Paul A, Becker J, Hoyer PF. Sirolimus rescue of renal failure in children after combined liver-kidney transplantation. <i>Pediatric Nephrology</i> 2005;20(5):686-9.</p> <p>Casas-Melley AT, Falkenstein KP, Flynn LM, Ziegler VL, Dunn SP. Improvement in renal function and rejection control in pediatric liver transplant recipients with the introduction of sirolimus. <i>Pediatr Transplant</i> 2004;8(4):362-6.</p> <p>Trapianti pediatrici di rene e fegato</p> <p>Sindhi R, Seward J, Mazariegos G, Soltys K, Seward L, Smith A, et al. Replacing calcineurin inhibitors with mTOR inhibitors in children. <i>Pediatric Transplantation</i> 2005;9(3):391-397.</p> <p>Vester U, Kranz B, Nadalin S, Paul A, Becker J, Hoyer PF. Sirolimus rescue of renal failure in children after combined liver-kidney transplantation. <i>Pediatric Nephrology</i> 2005;20(5):686-9.</p> <p>Casas-Melley AT, Falkenstein KP, Flynn LM, Ziegler VL, Dunn SP. Improvement in renal function and rejection control in pediatric liver transplant recipients with the introduction of sirolimus. <i>Pediatr Transplant</i> 2004;8(4):362-6.</p> <p>Markiewicz M, Kalicinski P, Teisseyre J, Ismail H, Kaminski A, Teisseyre M. Rapamycin in children after liver transplantation. <i>Transplant Proc</i> 2003;35(6):2284-6.</p> <p>Trapianti di midollo</p> <p>(GVHD-Stem cell transplantation-malignancy-pediatric).Cutler C, Antin JH. Sirolimus for GVHD prophylaxis in allogeneic stem cell transplantation. <i>Bone Marrow Transplant</i> 2004;34(6):471-6.Rapamycin (sirolimus) for treatment of chronic graft-versus-host disease. <i>Biol Blood Marrow Transplant.</i> 2005; 11: 1: 47-55. Marty FM, Lowry CM, Cutler CS, Campbell BJ, Fiumara K, Baden LR, et al. Voriconazole and Sirolimus Coadministration after Allogeneic Hematopoietic Stem Cell Transplantation. <i>Biol Blood Marrow Transplant</i> 2006;12(5):552-559.</p> <p>Trapianto di pancreas, cuore, polmone</p> <p>Toso C, Baertschiger R, Morel P, Bosco D, Armanet M, Wojtusciszyn A, et al. Sequential kidney/islet transplantation: efficacy and safety assessment of a steroid-free immunosuppression protocol. <i>Am J Transplant</i> 2006;6(5):1049-58.</p> <p>Knight RJ, Kerman RH, Zela S, Podbielski J, Podder H, Van Buren CT, et al. Pancreas transplantation utilizing thymoglobulin, sirolimus, and cyclosporine. <i>Transplantation</i> 2006;81(8):1101-5.</p> <p>Gleissner CA, Doesch A, Ehlermann P, Koch A, Sack FU, Katus HA, et al. Cyclosporine Withdrawal Improves Renal Function in Heart Transplant Patients on Reduced-Dose Cyclosporine Therapy. <i>Am J Transplant</i> 2006.</p> <p>Vazquez de Prada JA, Vilchez FG, Cobo M, Ruisanchez C, Valls MF, Ruano J, et al. Sirolimus in de novo heart transplant recipients with severe renal impairment. <i>Transplant International</i> 2006;19(3):245-248.</p> <p>Bestetti R, Theodoropoulos TA, Burdmann EA, Filho MA, Cordeiro JA, Villafanha D. Switch from Calcineurin Inhibitors to Sirolimus-Induced Renal Recovery in Heart Transplant Recipients in the Midterm Follow-up. <i>Transplantation</i> 2006;81(5):692-696.</p> <p>Laporta Hernandez R, Ussetti Gil P, Garcia Gallo C, de Pablo Gafas A, Carreno Hernandez MC, Ferreira Alvarez MJ. Rapamycin in Lung Transplantation. <i>Transplant Proc</i> 2005;37(9):3999-4000.</p> <p>Sanchez EQ, Martin AP, Ikegami T, Uemura T, Narasimhan G, Goldstein RM, et al. Sirolimus conversion after liver transplantation: improvement in measured glomerular filtration rate after 2 years. <i>Transplant Proc</i></p>

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		<p>2005;37(10):4416-23.</p> <p>Trapianto di isole di Langerhans</p> <p>Shapiro AMJ, Lakey JRT, Ryan EA, Korbutt GS, Toth EL, Warnock GL, Kneteman NM, Rajotte RV: Islet transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. <i>N Engl J Med</i> ; 343:230-238</p> <p>Shapiro AMJ, Ricordi C, Hering BJ et al: International trial of the Edmonton Protocol for islet transplantation. <i>N Engl J Med</i> 2006; 355: 1318-30,</p> <p>Froud T, Baidal DA, Ponte G, Ferreira DV, Ricordi C, Alejandro R: Resolution of neurotoxicity and beta-cell toxicity in an islet transplant recipient following substitution of tacrolimus with MMF. <i>Cell transplant</i> 2006, 15 (7): 613-629</p>
Tacrolimus	<p>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 multiviscerale</p>	<p>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</p> <p><u>Profilassi Tx polmone:</u></p> <ul style="list-style-type: none"> - Treede et Al, 3rd ICI San Diego, US, 2004; abstract 22 - Keenan et Al, Ann Thoracic Surg 1995,60:580 - Treede et Al, J Heart Lung Transplant 2001; 20:511 <p><u>Profilassi Tx Rene pancreas e pancreas:</u></p> <ul style="list-style-type: none"> - Bechstein et Al, Transplantation 2004;7:1221 - J Malaise et Al and EUROSPK Study Group, Transplantation Proceedings 2005 37,2843-2845 - F Saudek and the SPK Study Group, Nephrology Dialysis Transplantation 2005 <p><u>Profilassi Tx Intestino-Multiviscerale:</u></p> <p>Abu Elmagd et Al, Ann Surg 2001;234:404</p> <p><u>Trapianto di Midollo:</u></p> <ul style="list-style-type: none"> - Koehler MT et Al Bone Marrow Transplantation 1995 15:895 - Kananaru A et Al for the Japanese FK 506 Study Group; Bone Marrow Transplantation 1995 15:885 - Nash R.A et Al Blood 1995 85: 3746 - Nash R.A et Al Blood 1996 88:3634 - Nash R.A et Al Blood 2000 96:2062-2068 <p>Trapianto di isole di Langerhans</p> <p>Shapiro AMJ, Lakey JRT, Ryan EA, Korbutt GS, Toth EL, Warnock GL, Kneteman NM, Rajotte RV: Islet transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. <i>N Engl J Med</i> ; 343:230-238</p> <p>Shapiro AMJ, Ricordi C, Hering BJ et al: International trial of the Edmonton Protocol for islet transplantation. <i>N Engl J Med</i> 2006; 355: 1318-30,</p>

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		<p>Tutte le indicazioni anche in associazione con altri farmaci ad attività immunosoppressiva o immunomodulante e/o steroide.</p> <p><u>Bibliografia associazioni:</u> Generale: Undre N., Nephrol Dial Transplant (2003) 18 [Suppl 1]: i12-i15; Andreoni KA et al., American Journal of Transplantation 2007; 7 (Part 2): 1359-1375; Guerra G. et al., Transplant International ISSN 0934-0874; Webster A. et al., BMJ, doi:10.1136/bmj.38569.471007 Micofenolato Mofetile (MMF): Vitko S. et al., Transplantation 2005;80: 1734-1741; Squifflet JP et al., Transplantation Proceedings, 34, 1584-1586 (2002); Rostaing L. et al., Transplantation • Volume 79, Number 7, April 15, 2005; Mc Taggart S., NEPHROLOGY 2007; 12, S106-S110; Augustine j.j. et al., Transplantation 2006;81: 1004-1009; H.T. Silva et al., American Journal of Transplantation 2007; 7: 595-608; Ekberg H. et al., N Engl J Med 2007;357:2562-75; McAlister H. et al., Cochrane Database of Systematic Reviews 2006, Issue 4. Art. No.: CD005161. DOI: 10.1002/14651858.CD005161.pub2; Pageaux GP. Et al., LIVER TRANSPLANTATION 12:1755-1760, 2006; Grimm M. et al., American Journal of Transplantation 2006; 6: 1387-1397; Kobashigawa JA et al., American Journal of Transplantation 2006; 6: 1377-1386; Bravo C. et al., Transplantation Proceedings, 39, 2409-2412 (2007); Gallon LG et al., Transplantation 2007;83: 1324-1329 Acido Micofenolico: Budde K. Et al., Transplantation 2007;83: 417-424 Sirolimus: Vitko S. et al., Transplantation 2005;80: 1734-1741; ; Augustine j.j. et al., Transplantation 2006;81: 1004-1009; ; Kobashigawa JA et al., American Journal of Transplantation 2006; 6: 1377-1386; Ciancio G. et al., Transplantation 2006;81: 845-852 Everolimus: Chan L. et al., Transplantation 2008;85: 821-826; Kovarik JM et al., Transplantation Proceedings, 38, 3456-3458 (2006) Azatioprina: Grimm M. et al., American Journal of Transplantation 2006; 6: 1387-1397; Bravo C. et al., Transplantation Proceedings, 39, 2409-2412 (2007); Jessupp M et al., Curr. Opin.in organ Transplantation 12: 536-542 (2007) Anticorpi (mono o policlonali): Boillot O. et al., Liver Transplantation, Vol 11, No 1 (January), 2005: pp 61-67; H.T. Silva et al., American Journal of Transplantation 2007; 7: 595-608; Kobashigawa JA et al., American Journal of Transplantation 2006; 6: 1377-1386; Rostaing L. et al., Transplantation • Volume 79, Number 7, April 15, 2005; Bravo C. et al., Transplantation Proceedings, 39, 2409-2412 (2007); Maudgil A et al., Pediatr. Drugs 2007 9(5)</p>
<p>Thymoglobuline ATC: L04AA04</p>	<p>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</p>	<p>Profilassi nell'adulto della malattia acuta e cronica da trapianto verso ospite (GvHD) nel trapianto da donatore familiare immunocompatibile (HLA identico)</p> <p>1) Once-Daily Intravenous Busulfan Given with Fludarabine as Conditioning for Allogeneic Stem Cell Transplantation: Study of Pharmacokinetics and Early Clinical Outcomes J. A. Russell, H. T. Tran, D. Quinlan, A. Chaudhry, P. Duggan, C. Brown, D. Stewart, J. D. Ruether, D. Morris, S. Glück, E. Gyonyor, B. S. Andersson <i>Biology of Blood and Marrow Transplantation</i> 8:468-476 (2002)</p> <p>2) Graft-versus-host disease following allogeneic transplantation from HLA-identical sibling with antithymocyte globulin-based reduced-intensity preparative regimen Mohamad Mohty, Jacques-Olivier Bay, Catherine Faucher, Bachra Choufi, Karin Bilger, Olivier Tournilhac, Norbert Vey, Anne-Marie Stoppa, Diane Coso, Christian Chabannon, Patrice Viens, Dominique Maraninchi, and Didier Blaise.</p>

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		<p><i>Blood</i>, 15 July 2003 - Vol 102, Number 2</p> <p>3) Antithymocyte globulin affects the occurrence of acute and chronic graft-versus-host disease after a reduced-intensity conditioning regimen by modulating mixed chimerism induction and immune reconstitution. Nakai K, Mineishi S, Kami M, Saito T, Hori A, Kojima R, Imataki O, Hamaki T, Yoshihara S, Ohnishi M, Kim SW, Ando T, Fumitoh A, Kanda Y, Makimoto A, Tanosaki R, Kanai S, Heike Y, Ohnishi T, Kawano Y, Wakasugi H, Takaue Y. <i>Transplantation</i> 2003 Jun 27;75(12):2135-43</p> <p>4) Reduced-intensity preparative regimen and allogeneic stem cell transplantation for advanced solid tumors Blaise D, Bay JO, Faucher C, Michallet M, Boiron JM, Choufi B, Cahn JY, Gratecos N, Sotto JJ, François S, Fleury J, Mohty M, Chabannon C, Bilger K, Gravis G, Viret F, Braud AC, Bardou VJ, Maraninchi D, Viens P. <i>Blood</i> 2004 Jan 15;103(2):435-41</p> <p>5) Protective Conditioning for Acute Graft-versus-Host Disease Robert Lowsky, M.D., Tsuyoshi Takahashi, M.D., Ph.D., Yin Ping Liu, M.D., Sussan Dejbakhsh-Jones, M.S., F. Carl Grumet, M.D., Judith A. Shizuru, M.D., Ph.D., Ginna G. Laport, M.D., Keith E. Stockerl-Goldstein, M.D., Laura J. Johnston, M.D., Richard T. Hoppe, M.D., Daniel A. Bloch, Ph.D., Karl G. Blume, M.D., Robert S. Negrin, M.D., and Samuel Strober, M.D. <i>N Engl J Med</i> Sept 29, 2005 353;13</p> <p>6) Reduced Incidence of Acute and Chronic Graft-versus-Host Disease with the Addition of Thymoglobulin to a Targeted Busulfan/Cyclophosphamide Regimen H. Joachim Deeg, Barry E. Storer, Michael Boeckh, Paul J. Martin, Jeannine S. McCune, David Myerson, Shelly Heimfeld, Mary E. Flowers, Claudio Anasetti, Kristine C. Doney, John A. Hansen, Hans-Peter Kiem, Richard A. Nash, Paul V. O'Donnell, Jerald P. Radich, Brenda M. Sandmaier, Bart L. Scott, Mohamed L. Sorror, E. Houston Warren, Robert P. Witherspoon, Ann Woolfrey, Frederick R. Appelbaum, Rainer Storb. <i>Biology of Blood and Marrow Transplantation</i> 12:573-584 (2006)</p> <p>7) Allogeneic transplantation for adult acute leukemia in first and second remission with a novel regimen incorporating daily intravenous busulfan, fludarabine, 400 CGY total-body irradiation, and Thymoglobulin Russell JA, Savoie ML, Balogh A, Turner AR, Larratt L, Chaudhry MA, Storek J, Bahlis NJ, Brown CB, Quinlan D, Geddes M, Stewart DA. <i>Biol Blood Marrow Transplant.</i> 2007 Jul;13(7):814-21</p> <p>8) Adult Recipients of Matched Related Donor Blood Cell Transplants Given Myeloablative Regimens Including Pretransplant Antithymocyte Globulin Have Lower Mortality Related to Graft-versus-Host Disease: A Matched Pair Analysis James A. Russell, A. Robert Turner, Loree Larratt, Ahsan Chaudhry, Donald Morris, Christopher Brown, 1,2 Diana Quinlan, Douglas Stewart <i>Biology of Blood and Marrow Transplantation</i> 13:299-306 (2007)</p>
Valganciclovir	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.	<p>Trapianto midollo osseo; trapianto d'organo solido pediatrico</p> <p>BMT Winston DJ et al. Pharmacokinetics of ganciclovir after oral valganciclovir versus intravenous ganciclovir in allogeneic stem cell transplant patients with graft-versus-host disease of the gastrointestinal tract. <i>Biol Blood Marrow Transplant</i> 2006; 12 (6): 635-40 <i>The pharmacokinetics of ganciclovir after oral valganciclovir versus intravenous ganciclovir were compared in</i></p>

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		<p><i>allogeneic stem cell transplant recipients with stable graft-versus-host disease of the gastrointestinal tract. Oral valganciclovir could be a useful alternative to intravenous ganciclovir in certain stable stem cell transplant patients who require prophylaxis or preemptive therapy for cytomegalovirus infection.</i></p> <p>Ayala E et al. Valganciclovir is safe and effective as pre-emptive therapy for CMV infection in allogeneic hematopoietic stem cell transplantation. Bone Marrow Transplant 2006; 37 (9): 851-6</p> <p><i>Pre-emptive therapy of CMV infection with oral VGC is safe and effective in allogeneic HSCT recipients.</i></p> <p>Van der Heiden PLJ et al. Oral valganciclovir as pre-emptive therapy has similar efficacy on cytomegalovirus DNA load reduction as intravenous ganciclovir in allogeneic stem cell transplantation recipients. Bone Marrow Transplant 2006; 37 (7): 693-8</p> <p><i>The efficacy and safety of oral valganciclovir was compared to ganciclovir i.v. in pre-emptive treatment of cytomegalovirus (CMV) in T-cell-depleted allogeneic stem cell transplant (allo-SCT) recipients. In conclusion, pre-emptive treatment with valganciclovir and ganciclovir, led to similar reduction of CMV DNA load. Oral valganciclovir is an attractive and safe alternative for pre-emptive CMV treatment in T-cell-depleted allo-SCT recipients.</i></p> <p>Einsele H et al. Oral valganciclovir leads to higher exposure to ganciclovir than intravenous ganciclovir in patients following allogeneic stem cell transplantation. Blood 2006; 107 (7): 3002-8</p> <p><i>This supports the use of V-GCV in SCT, even in patients with I-GVHD grades I-II. Due to higher exposure after V-GCV compared with IV-GCV, patients should be monitored carefully for safety reasons.</i></p> <p>Boeckh M et al. Cytomegalovirus in hematopoietic stem cell transplant recipients: Current status, known challenges, and future strategies. Biol Blood Marrow Transplant 2003; 9 (9): 543-58</p> <p><i>Strategies currently being investigated include long-term suppression of CMV with valganciclovir for the prevention of late CMV infection and disease, adoptive transfer of CMV-specific T cells, and donor and recipient vaccination strategies.</i></p> <p>Infezione da Cytomegalovirus in pazienti pediatrici con trapianto</p> <p>Clark BS et al. Valganciclovir for the prophylaxis of cytomegalovirus disease in pediatric liver transplant recipients. Transplantation. 2004; 77 (9): 1480</p> <p>Burri M et al. Oral valganciclovir in children: single dose pharmacokinetics in a six-year-old girl. Ped Infectious Dis J 2004; 23 (3): 263-266</p> <p>Razonable RR, Paya CV. Valganciclovir for the prevention and treatment of cytomegalovirus disease in immunocompromised hosts. Expert Rev. Anti-infect. Ther. 2004; 2 (1): 27-42)</p> <p>Vaudry W et al. Safeto of oral valganciclovir powder for oral solution in pediatric solid organ transplant recipients. Am J Transplant / Transplantation 2006 WTC 215 Abs 441</p> <p>Bouw R et al. Ganciclovir pharmacokinetics in pediatric solid organ transplant recipients after administration of valganciclovir oral solution. Am J Transplant / Transplantation 2006 WTC 215 Abs 442.</p>