Dear Sir or Madam,

As a compendium recognized by the Centers for Medicare and Medicaid Services (CMS), Medicare Part D plans utilize the information in Micromedex® DRUGDEX® for determination of medically-accepted off-label indications. This determination is critical, as it dictates whether a drug claim will be reliably paid by a Medicare Part D plan for a specific beneficiary. Current monographs for many immunosuppressive drugs in Micromedex® DRUGDEX® do not adequately address off-label organ transplant uses. As a result, transplant recipients are vulnerable to, and some have experienced, denial of coverage by Part D plans for their lifesaving immunosuppressive drug therapy.

The American Society of Transplantation became aware of this issue in 2016 and formalized a position (Appendix A). We have written to alert you of this issue once before, on April 10, 2019. We recognize and appreciate that you have since added “liver transplant rejection, prophylaxis” an appropriate off-label indication for mycophenolate sodium. Several additional updates are needed.

Per our proposed approaches for resolution, we hereby implore you to review your Micromedex® DRUGDEX® content on the following drugs, and consider expanding your “Non-FDA Uses” section to include the off-label indications listed below (these are also summarized in Appendix B):

1. Tacrolimus
   a. Add vascular composite allograft rejection, prophylaxis
2. Cyclosporine
   a. Add pancreas transplant rejection, prophylaxis
3. Mycophenolate mofetil
   a. Add lung transplant rejection, prophylaxis
   b. Add pancreas transplant rejection, prophylaxis
   c. Add intestine transplant rejection, prophylaxis
   d. Add vascular composite allograft rejection, prophylaxis
4. Mycophenolate sodium
   a. Add heart transplant rejection, prophylaxis
   b. Add lung transplant rejection, prophylaxis
   c. Add pancreas transplant rejection, prophylaxis
   d. Add vascular composite allograft rejection, prophylaxis
5. Azathioprine
   a. Add heart transplant rejection, prophylaxis
   b. Add lung transplant rejection, prophylaxis
   c. Add intestine transplant rejection, prophylaxis
   d. Add vascular composite allograft rejection, prophylaxis

6. Leflunomide
   a. Add kidney transplant rejection, prophylaxis
   b. Add liver transplant rejection, prophylaxis

7. Prednisone/Prednisolone
   a. Add liver transplant rejection, prophylaxis
   b. Add lung transplant rejection, prophylaxis
   c. Add pancreas transplant rejection, prophylaxis
   d. Add intestine transplant rejection, prophylaxis
   e. Add vascular composite allograft rejection, prophylaxis

8. Sirolimus
   a. Add liver transplant rejection, prophylaxis
   b. Add heart transplant rejection, prophylaxis
   c. Add lung transplant rejection, prophylaxis
   d. Add pancreas transplant rejection, prophylaxis
   e. Add intestine transplant rejection, prophylaxis
   f. Add vascular composite allograft rejection, prophylaxis

9. Everolimus
   a. Add heart transplant rejection, prophylaxis
   b. Add lung transplant rejection, prophylaxis
   c. Add pancreas transplant rejection, prophylaxis
   d. Add vascular composite allograft rejection, prophylaxis

10. Belatacept
    a. Add liver transplant rejection, prophylaxis
    b. Add heart transplant rejection, prophylaxis
    c. Add lung transplant rejection, prophylaxis
    d. Add pancreas transplant rejection, prophylaxis
    e. Add intestine transplant rejection, prophylaxis
    f. Add heart transplant, pre-transplant desensitization

11. Basiliximab
    a. Add heart transplant rejection, prophylaxis
    b. Add lung transplant rejection, prophylaxis
    c. Add pancreas transplant rejection, prophylaxis
    d. Add intestine transplant rejection, prophylaxis
    e. Add vascular composite allograft rejection, prophylaxis

12. Rabbit antithymocyte globulin
    a. Add liver transplant rejection, prophylaxis
    b. Add intestine transplant rejection, prophylaxis
    c. Add vascular composite allograft rejection, prophylaxis
    d. Add liver transplant rejection, treatment
    e. Add lung transplant rejection, treatment
    f. Add vascular composite allograft rejection, treatment

13. Alemtuzumab
    a. Add heart transplant rejection, prophylaxis
    b. Add lung transplant rejection, prophylaxis
    c. Add pancreas transplant rejection, prophylaxis
    d. Add intestine transplant rejection, prophylaxis
e. Add vascular composite allograft rejection, prophylaxis
f. Add kidney transplant rejection, treatment
g. Add lung transplant rejection, treatment
h. Add vascular composite allograft rejection, treatment

14. Immune globulin
a. Add liver transplant rejection, treatment
b. Add heart transplant rejection, treatment
c. Add lung transplant rejection, treatment
d. Add pancreas transplant rejection, treatment
e. Add intestine transplant rejection, treatment
f. Add vascular composite allograft rejection, treatment
g. Add liver transplant, pre-transplant desensitization
h. Add heart transplant, pre-transplant desensitization
i. Add intestine transplant, pre-transplant desensitization

15. Rituximab
a. Add intestine transplant rejection, prophylaxis
b. Add kidney transplant rejection, treatment
c. Add liver transplant rejection, treatment
d. Add heart transplant rejection, treatment
e. Add lung transplant rejection, treatment
f. Add pancreas transplant rejection, treatment
g. Add intestine transplant rejection, treatment
h. Add vascular composite allograft rejection, treatment
i. Add kidney transplant, pre-transplant desensitization
j. Add liver transplant, pre-transplant desensitization
k. Add heart transplant, pre-transplant desensitization

16. Bortezomib
a. Add kidney transplant rejection, treatment
b. Add liver transplant rejection, treatment
c. Add heart transplant rejection, treatment
d. Add lung transplant rejection, treatment
e. Add pancreas transplant rejection, treatment
f. Add intestine transplant rejection, treatment
g. Add vascular composite allograft rejection, treatment
h. Add kidney transplant, pre-transplant desensitization
i. Add heart transplant, pre-transplant desensitization

17. Carfilzomib
a. Add lung transplant rejection, treatment
b. Add kidney transplant, pre-transplant desensitization
c. Add heart transplant, pre-transplant desensitization

18. Eculizumab
a. Add heart transplant rejection, prophylaxis
b. Add kidney transplant rejection, treatment
c. Add liver transplant rejection, treatment
d. Add heart transplant rejection, treatment
e. Add lung transplant rejection, treatment
f. Add pancreas transplant rejection, treatment
g. Add intestine transplant rejection, treatment
h. Add vascular composite allograft rejection, treatment
i. Add kidney transplant, pre-transplant desensitization
19. Tocilizumab
   a. Add kidney transplant rejection, treatment
   b. Add kidney transplant, pre-transplant desensitization
20. Adalimumab
   a. Add intestine transplant rejection, treatment
21. Infliximab
   a. Add intestine transplant rejection, treatment

We realize that you require at least one citation from the medical literature to support each of these revisions. We have reviewed the literature, and Appendix B contains the citations that we believe meet this need.

Thank you in advance for your attention to this matter.

Sincerely,

John Gill, MD, MS
President

Attachments:
- Appendix A: AST Position Statement on Immunosuppressant Drug Coverage Under Medicare Part D Benefit
- Appendix B: Overview of drug/indication pairs with on- or off-label indications already endorsed by Micromedex (green) and those for which we request endorsement (yellow)
- Appendix C: Citations from the medical literature in support of the proposed off-label indication
Appendix A:

AST Position Statement on Immunosuppressant Drug Coverage Under Medicare Part D Benefit

### Appendix B:

Overview of drug/indication pairs with on- or off-label indications already endorsed by Micromedex (green) and those for which we request endorsement (yellow)

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**To prevent rejection**

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**To treat rejection**

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**For pre-transplant desensitization**

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Adapted from Lexi-Drugs ® Level of Evidence Scale

A. Evidence from well performed randomized, controlled trials or overwhelming evidence of some other form to support the off-label use

B. Evidence from randomized, controlled trials with important limitations (e.g., inconsistent results, methodologic flaws, indirect, imprecise) or very strong evidence of some other research design

C. Evidence from observational studies (e.g., retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (e.g., when limited options exist for condition)
Appendix C:

Citations from the medical literature in support of the proposed off-label indication

1. Tacrolimus
   a. Add vascular composite allograft rejection, prophylaxis

2. Cyclosporine
   a. Add pancreas transplant rejection, prophylaxis


3. Mycophenolate mofetil

a. Add lung transplant rejection, prophylaxis

b. Add pancreas transplant rejection, prophylaxis

c. Add intestine transplant rejection, prophylaxis

d. Add vascular composite allograft rejection, prophylaxis


4. Mycophenolate sodium

   a. Add heart transplant rejection, prophylaxis


   b. Add lung transplant rejection, prophylaxis

   c. Add pancreas transplant rejection, prophylaxis


d. Add vascular composite allograft rejection, prophylaxis

5. Azathioprine

a. Add heart transplant rejection, prophylaxis

b. Add lung transplant rejection, prophylaxis

c. Add intestine transplant rejection, prophylaxis

d. Add vascular composite allograft rejection, prophylaxis

6. Leflunomide

a. Add kidney transplant rejection, prophylaxis

b. Add liver transplant rejection, prophylaxis

7. Prednisone/Prednisolone

a. Add liver transplant rejection, prophylaxis

b. Add lung transplant rejection, prophylaxis
   iii. Zuckermann A, Reichenspurner H, Birsan T, et al. Cyclosporine A versus tacrolimus in combination with mycophenolate mofetil and...


c. Add pancreas transplant rejection, prophylaxis

d. Add intestine transplant rejection, prophylaxis

e. Add vascular composite allograft rejection, prophylaxis


8. Sirolimus

a. Add liver transplant rejection, prophylaxis
   
   
   
   

b. Add heart transplant rejection, prophylaxis
   


c. Add lung transplant rejection, prophylaxis


d. Add pancreas transplant rejection, prophylaxis


e. Add intestine transplant rejection, prophylaxis

f. Add vascular composite allograft rejection, prophylaxis

9. Everolimus

a. Add heart transplant rejection, prophylaxis


b. Add lung transplant rejection, prophylaxis


c. Add pancreas transplant rejection, prophylaxis


d. Add vascular composite allograft rejection, prophylaxis

10. Belatacept

a. Add liver transplant rejection, prophylaxis

b. Add heart transplant rejection, prophylaxis

c. Add lung transplant rejection, prophylaxis

d. Add pancreas transplant rejection, prophylaxis

e. Add vascular composite allograft rejection, prophylaxis


f. Add heart transplant, pre-transplant desensitization

11. Basiliximab

a. Add heart transplant rejection, prophylaxis

b. Add lung transplant rejection, prophylaxis

c. Add pancreas transplant rejection, prophylaxis

d. Add intestine transplant rejection, prophylaxis

e. Add vascular composite allograft rejection, prophylaxis
12. Rabbit antithymocyte globulin

a. Add liver transplant rejection, prophylaxis

b. Add intestine transplant rejection, prophylaxis

vi. Add vascular composite allograft rejection, prophylaxis
d. Add liver transplant rejection, treatment

e. Add lung transplant rejection, treatment

f. Add vascular composite allograft rejection, treatment

13. Alemtuzumab

a. Add heart transplant rejection, prophylaxis

b. Add lung transplant rejection, prophylaxis

c. Add pancreas transplant rejection, prophylaxis

d. Add intestine transplant rejection, prophylaxis

e. Add vascular composite allograft rejection, prophylaxis

f. Add kidney transplant rejection, treatment

g. Add lung transplant rejection, treatment

h. Add vascular composite allograft rejection, treatment


14. Immune globulin

a. Add liver transplant rejection, treatment


b. Add heart transplant rejection, treatment


c. Add lung transplant rejection, treatment


d. Add pancreas transplant rejection, treatment

e. Add intestine transplant rejection, treatment

f. Add vascular composite allograft rejection, treatment

g. Add liver transplant, pre-transplant desensitization

h. Add heart transplant, pre-transplant desensitization

i. Add intestine transplant, pre-transplant desensitization

15. Rituximab

a. Add intestine transplant rejection, prophylaxis

b. Add kidney transplant rejection, treatment

c. Add liver transplant rejection, treatment

d. Add heart transplant rejection, treatment
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e. Add lung transplant rejection, treatment

f. Add pancreas transplant rejection, treatment

g. Add intestine transplant rejection, treatment

h. Add vascular composite allograft rejection, treatment

i. Add kidney transplant, pre-transplant desensitization

j. Add liver transplant, pre-transplant desensitization
k. Add heart transplant, pre-transplant desensitization


16. Bortezomib

a. Add kidney transplant rejection, treatment


b. Add liver transplant rejection, treatment
   


c. Add heart transplant rejection, treatment
   


d. Add lung transplant rejection, treatment
   


e. Add pancreas transplant rejection, treatment

f. Add intestine transplant rejection, treatment

g. Add vascular composite allograft rejection, treatment

h. Add kidney transplant, pre-transplant desensitization


i. Add heart transplant, pre-transplant desensitization

17. Carfilzomib

a. Add lung transplant rejection, treatment

b. Add kidney transplant, pre-transplant desensitization

c. Add heart transplant, pre-transplant desensitization

18. Eculizumab

a. Add heart transplant rejection, prophylaxis
b. Add kidney transplant rejection, treatment

c. Add liver transplant rejection, treatment

d. Add heart transplant rejection, treatment

e. Add lung transplant rejection, treatment

f. Add pancreas transplant rejection, treatment

g. Add intestine transplant rejection, treatment

h. Add vascular composite allograft rejection, treatment

i. Add kidney transplant, pre-transplant desensitization

19. Tocilizumab

a. Add kidney transplant rejection, treatment

b. Add kidney transplant, pre-transplant desensitization

20. Adalimumab

a. Add intestine transplant rejection, treatment

21. Infliximab

a. Add intestine transplant rejection, treatment