

TRANSPLANT NEWS

Akron-Canton Transplant Recipients

2014 Schedule of Events

Monthly meeting from 6:30 to 8:30 on the 3rd Tuesday of every month at Education Building "A" at the North Canton Medical Center.

OrganDonorSabbath on April 25, 2014 at 7:30 at Akron Temple Israel. This will be the 5th annual service sponsored by Micki Wise and the Wise Family in memory of Bernard Wise.

Hartville Flea Market, June, 2014. See Sue & Ray Golden for donation details and visit them at the flea market.

Lifebanc August, 2014 Gift of Life Walk & Run August 9, 2014 at Blossom Music Center. Join Amanda's or Rosie & Pat's team or Alison Werstler's Hearts for Ray Stiles and support Lifebanc.

Celebration of Life Picnic, August 10, 2014 from noon to 4:00 at the John Torok Community Center, Green, Ohio.

November 2014 Akron Children's Hospital Holiday Tree Festival at John S Knight Center. Please contact Rosie or Sue if you have a tree or items for this year's squirrel theme tree.

Holiday Celebration of Life Dinner on December 16th from 6:30 to 9:00 at NCMC. Donor recognition will be followed by dedication of ornaments by organ recipients or their loved ones.

Member update

Rosie Price is recovering from shingles at her mom's and Don Gordon has had knee surgery. Please keep them in your thoughts

My understanding of what is happening with:

No organ transplant rejection drugs in Medicare Part D formularies in 2015

We would like to ask for your assistance to stop the proposed change in Medicare Part D. "All or virtually all" Immunosuppressant (rejection) drugs are currently required for all Medicare Part D drug formularies.

CMS (Centers for Medicare & Medicaid Services) as part of the Affordable Care Act is proposing to remove immunosuppressant drugs as required drugs from Medicare Part D Formularies effective 1-1-15.

Present Status

Medicare Part D currently requires all Part D formularies to include "all or substantially all" drugs within six protected drug classes: Anti-Neoplastics (Chemotherapy), Anti Convulsants (Epilepsy), Anti-Retrovirals (HIV/AIDS), Anti-Psychotics (Psychosis), Anti-Depressants (Depression) and Immunosuppressants (Transplants).

Two Part Test used by CMS

1/ The drug therapy cannot be delayed more than 7 days because of the risk of hospitalization, incapacity, disability or death

2/ More specific CMS formulary requirements (specific brand/generic drugs) will not meet all the requirements of the disease (diversity of conditions and variability of drug therapies required)

CMS justification for the proposed change

1/ Anti-Neoplastics, Anti Convulsants & Anti-Retrovirals meet both parts of the test and will continue to be protected. Anti-Depressants & Anti-Psychotics do not meet either part 1 or part 2.

Action on these two drugs will be deferred.

Immunosuppressants meet the risk of disability or death requirements to be protected. Transplant treatment guide lines recommend subclasses of drugs rather than specific individual drugs **Different drug "cocktails" are used for each type of organ transplant and for recipients of the same organ depending on their reaction to the treatment.**

2/. \$720 million savings are projected for 2016 through 2019, mostly for Anti-Psychotics. **There is no cost savings data or any impacts for transplant rejection drugs. Immunosuppressants protection will be removed 1-1-15.**

3/ A CMS panel studied a representative Anti-Depressant & Anti-Psychotic formulary (16 brand drugs and

41 generic drugs) and concluded that 100% of the brand and 63% of the generic drugs could be eliminated and formulary standards could be met with 9 generic Anti-Depressants and 6 Anti-Psychotics. **Immunosuppressants do not meet the normal Brand/Generic step therapy drug model CMS uses for cost reductions.**

4/ CMS states that typical formulary reviews and drug exception appeal standards would assure transplant recipients will have access to their rejection medication. **The reality of the appeals process is that it is too complex and the amount of time required for an exception appeal would take too long for a transplant recipient to survive**

E. Availability of Immunosuppressants under Medicare part B as an alternate source was discussed. CMS suggested that Immunosuppressants provided by part B could be removed from Part D formularies. **Part B only provides drugs for patients whose transplant was paid for by Medicare.**

Additional considerations

A. If CMS believes the formulary review process is adequate to protect transplant recipients, why maintain any protected class of drugs. **Why do a total removal of the Immunosuppressants protection without a study of the effects or starting with a phased change to assess the impact of the change?**

B. Medicare Part D is renewed every year. Coverage is regional (multi county, not state/country wide) and

providers change yearly. Transplant recipients will have to join a part D plan with the probability of yearly prior authorization/step approvals. Request exception approval for Immunosuppressants not on the new formulary will be required every year. **There will be unknown impact on tier pricing, gap (donut hole) coverage and catastrophic coverage when out of pocket costs exceed the maximums.**

C. The probability is high that reviews will not be timely, drug shipments will exceed the 7 day requirements of test #1 and patient and medical provider costs will rise.

D. The reality is that the proposed changes to Medicare part D formularies will **become the defacto standard for all medical plans and will impact all medical drug plans.**

The bottom line is that **people will die.**

Conclusion

CMS claims that typical formulary reviews and the formulary exception appeal process will assure that transplant recipients will have access to their drugs. However, we know how complex and confusing drug reviews and appeals are and with no guarantee that an exception will be granted in a timely manner and at what cost to the recipient.

This change will initially effect the transplant community, but since the Medicare formulary is the de-facto standard for all medical insurance, this change will eventually impact all of us.

Medicare must continue to cover these critical drugs.

Please help us reverse this negative change. Comments on the proposed changes must be received by March 7th. We apologize for the short time left for comments to be made, but it took me this long to understand the 157 pages of the Federal Register that include this proposal.

We would be happy to answer any further questions, Please contact us at 330-497-7815 or wwh99@aol.com

Nancy & Walt Hinkel

Information links:

Want to read the proposed rule CMS-4159-P, go to:

<http://www.regulations.gov/#!docketDetail;D=CMS-2014-0007>

Want to comments on the proposed changes? **Comments must be received no later than 5 p.m. on March 7, 2014**

Write to Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4159-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Comment online at:

<http://www.regulations.gov/#!submitComment;D=CMS-2014-0007-0002>

Write your Congressman and Senators:

<http://www.contactingthecongress.org/>

About TRIO (Transplant Recipients International Organization)

Website: www.trioweb.org

TRIO's MISSION

TRIO is a non-profit organization improving the quality of lives touched by the miracle of transplantation through support, advocacy, education and awareness.

Support

We provide support to transplant candidates, recipients and their families, donors and donor families to help alleviate the stresses and problems associated with the process.

Advocacy

We make the concerns and needs that affect the welfare of transplant candidates, recipients, and donor families known to federal government bodies. We also effectively communicate the views of transplant candidates, recipients and their families, donors and donor families to the general public.

Education

We provide current information (with respect to developments in organ and tissue donation, transplantation, medications, social issues, and finances) to transplant candidates, recipients and their families, donors and donor families about initiatives and protocols in the field of transplantation.

Awareness

We promote organ and tissue donation as an important social responsibility. We develop and support mechanisms to improve the availability of organs and tissues on an equitable basis to meet the need of transplant candidates.

Editor: Nancy & Walt Hinkel
330-497-7815
wwh99@aol.com

Secretary: Mary Fread
1529 19th St NE
Canton, Oh 44714-2105
330-453-8214
transplant@neo.rr.com