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PROTOCOL TITLE: Denovo Belatacept In People Living With HIV (PLWH) After Kidney Transplant							
APPLICABLE FACILITIES:							
☐EHC	☐EDH	☐EHH	☐EHI	☐EHN	☐EJCH	☐ELTAC	☒ESJH
☒EUH	☐EUHM	☐EUHS	☐EUOSH	☐EWWH	☐RJV-ERH	☐RJV-ESOP	☐TEC/ESA
EFFECTIVE DATE: 09/12/2023				**ORIGINATION DATE:** 03/29/2023			

CATEGORY:
Therapeutic

LEVEL:
Independent

CONTENT:

Purpose:
To develop a protocol for denovo use of Belatacept in people living with HIV(PLWH) with Kidney transplant

Background:
Patient and graft survival in people living with HIV(PLWH) after kidney transplantation has dramatically improved over the years. The rate of rejection in PLWH with kidney transplant is higher than non -HIV transplant recipients. This is either due to a dysregulated immune response or fear of infection leading to usage of lower doses of immunosuppressive medication.
Most centers use Calcineurin inhibitor (CNI; eg, tacrolimus), an antimetabolite (eg, mycophenolate) and prednisone as the immunosuppression regimen of choice for PLWH with kidney transplant. Belatacept is known to have superior patient and allograft survival in comparison to CNIs (1). Limited retrospective data available on the use of Belatacept in PLWH with kidney transplant has shown superior allograft function and survival without significant increase in infection risk when compared to CNI use in PLWH with kidney transplant (2-4).

RELATED POLICIES / PROCEDURES:
The purpose of this is to create a protocol for denovo use of Belatacept in PLWH after kidney transplantation.

Potential benefits:
- Decrease risk of CNI-related nephrotoxicity
- Minimize further metabolic complications (DM, dyslipidemia, weight gain) from CNI in a patient that is already at high risk for metabolic complications given antiretroviral treatment (ART) and steroid use
- Allow for more flexibility in ART regimens after tacrolimus wean (i.e. ability to use PIs).

Potential risks:
- Increase risk of infection.

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- Increase risk of rejection

PLWH with kidney transplant will be eligible for denovo use of Belatacept if they meet the following criteria.

Inclusion Criteria

- Kidney transplant recipients
- Age 18 and older
- EBV IgG positive
- HIV Viral load <50 copies
- CD4+ count > 15%

Exclusion Criteria

- Multi-organ transplant
- CMV high risk (D+/R-)
- Untreated LTBI (latent TB infection)
- Receipt of organ from HIV + donor
- H/o of recurrent Infections- UTI, PNAs
- h/o one of the following Opportunistic infections in the past: Cryptococcus, Coccidioidomycosis, Histoplasmosis, Blastomycosis, Tuberculosis, Disseminated mycobacterium avium or other NTM disease, Aspergillus or other mold infections, Nocardia, Bartonella, cryptosporidiosis, toxoplasmosis
- Significant anal, vulvar, or cervical dysplasia (AIN/VIN/CIN or higher) or other significant HPV-related disease
- Any history of PTLD, lymphoma or hematologic malignancy
- Other conditions not listed that the Transplant ID team feels makes the patient at higher risk for complications with Belatacept (Transplant Infectious Diseases will comment on a patient's eligibility for Belatacept during pre-transplant and immediate post-transplant evaluations).

Work flow

A. Pre-Transplant Evaluation/counseling
    - Eligibility to receive Belatacept post-transplant will be determined during the Pre-Transplant evaluation period.
    - All HIV patients see Transplant ID as part of kidney transplant candidacy evaluation process.
    - Part of Transplant ID consultation workflow will be to indicate in their consult note if a particular patient will be eligible to receive Belatacept.

B. Post-transplant Prophylaxis
    - CMV: Valgancyclovir Prophylaxis for 6 months if moderate risk CMV, acyclovir PPX for 3 months if CMV R-/D-
    - PJP: trimethoprim/sulfamethoxazole Prophylaxis for 12 months (or alternative agent if Bactrim allergic/intolerant)

C. Post- Transplant Monitoring

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- HIV viral load- q monthly at Emory for 6 months, then q 3 months till month12 then back locally with their HIV provider
- CMV, BK monitoring monthly at least 1 year
- EBV monitoring every 3 months at least for 1 year
- ID appointments scheduled (1,2,3 months post-transplant then q 3 months until tac wean complete at 12 months) then back locally

REFERENCES AND SOURCES OF EVIDENCE:

1. Vincenti F, Rostaing L, Grinyo J, et.al. Belatacept and Long-Term Outcomes in Kidney Transplantation. N Engl J Med. 2016 Jan 28;374(4):333-43. doi: 10.1056/NEJMoa1506027. Erratum in: N Engl J Med. 2016 Feb 18;374(7):698. PMID: 26816011.
2. El Sakhawi K, Melica G, Scemla A, et.al. Belatacept-based immunosuppressive regimen in HIV-positive kidney transplant recipients. Clin Kidney J. 2020 Dec 16;14(8):1908-1914. doi: 10.1093/ckj/sfaa231. PMID: 34345414; PMCID: PMC8323145.
3. Santeusanio A, Bhansali A, De Boccardo G et.al. Conversion to Belatacept maintenance immunosuppression in HIV-positive kidney transplant recipients. Clin Transplant. 2020 Oct;34(10):e14041. doi: 10.1111/ctr.14041. Epub 2020 Aug 6. PMID: 32654239.
4. Tucker M, Palacios CFoppiano, Cohen E, et.al. Case-Control Study of Belatacept as Maintenance Immunosuppression in Kidney Transplant Recipients Living with HIV [abstract]. Am J Transplant. 2022; 22 (suppl 3). https://atcmeetingabstracts.com/abstract/case-control-study-of-Belatacept-as-maintenance-immunosuppression-in-kidney-transplant-recipients-living-with-hiv/. Accessed October 4, 2022.