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| **PROTOCOL TITLE: Kidney/Pancreas Post Transplant: Belatacept Conversion Protocol** |
| **APPLICABLE FACILITIES:** (Check all that apply) [x] EUH [ ] EUOSH [ ] EWWH [ ] EUHM [ ] EJCH [x] ESJH [x] TEC [ ] ESA [ ] ERH |
| **EFFECTIVE DATE:** 10/12/2018 | **ORIGINATION DATE: 10/6/11** |

**SCOPE:** All transplant program physicians, practitioners and clinical staff members are responsible for compliance with this clinical protocol.

**PURPOSE:** This protocol provides guidelines on the conversion of patients from a calcineurin inhibitor (CNI) based regimen to a belatacept based regimen.

**PROTOCOL:**

The Emory Transplant Center and all the solid organ transplant programs will comply with all applicable federal, state, and local laws, regulations, policies and protocols regarding the management of transplant patients.

**TARGET PATIENT POPULATIONS:**

Chronic allograft nephropathy (CAN) / Calcineurin inhibitor (CNI) toxicity on biopsy

Other CNI intolerance (TMA, Tremors, H/A, NODAT)

Patients who may benefit from long-term CNI avoidance

**CONVERSION CONSIDERATIONS:**

1. Patients must meet standard belatacept criteria as outlined in the renal transplant primary protocol. Belatacept screening should be documented in EeMR.

EBV positive serology

Kidney transplant only

No history of lymphoma, PTLD, or hematologic malignancy

No history of HIV

No IV access issues

No transportation limitations

1. Ensure adequate dosing of baseline immunosuppression (with the exception of the CNI agent that is being discontinued) during the conversion.
2. Patients at higher immunologic risk should be carefully considered prior to conversion:

Prior graft loss due to acute rejection

Recent acute rejection (within 3 months)

Banff 97 IIA or higher acute rejection

1. Women of child bearing potential who wish to pursue pregnancy post-transplant should be specifically counseled on risks versus benefits regarding conversion.
2. Financial implications of conversion to belatacept for the patient should be assessed and discussed with the patient.
3. Prior to conversion, belatacept conversion note must be documented in EeMR and belatacept coordinator notified (see attached workflow).

**IMMEDIATE CONVERSION SCHEDULE**

* For patients with toxicity necessitating immediate discontinuation of CNI (i.e. TMA)
* **Belatacept dosing**: Per package insert. Belatacept 10 mg/kg IVPB on day 1, day 5, day 14, month 1, month 2, and month 3. Reduce to 5mg/kg IVPB beginning month 4 and continue monthly thereafter.
* **CNI dosing**: Discontinue the first day belatacept is dosed

**< 1 YEAR POST-TRANSPLANT CONVERSION SCHEDULE**

* For patients with significant CNI toxicity or intolerances
* **Belatacept dosing**: Belatacept 10 mg/kg IVPB for first dose, then 5mg/kg monthly thereafter
* **CNI dosing:** Reduce tacrolimus trough to 5-8 ng/ml for 1month, then reduce to 3-5ng/ml for a minimum of 3 months **and** until at least 6 months post-transplant. Wean over 3 months per weaning table below

**> 1 YEAR POST-TRANSPLANT CONVERSION SCHEDULE**

* For patients with CNI toxicity, intolerance, or who may benefit from long-term CNI avoidance
* **Belatacept dosing**: Belatacept 10 mg/kg IVPB for first dose, then 5mg/kg monthly thereafter
* **CNI dosing:** Wean over 3 months per weaning table below
* **Labs:** Every other week labs for 4 months (or until 1 month after discontinuation of tacrolimus)

**Tacrolimus Weaning table**

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| Dose at time of wean | After 1st month, decrease to: | After 2nd month, decrease to: | After 3rd month: |
| 0.5 mg q12h (Prograf level < 5 ng/ml) | 0.5 mg daily | Discontinue | -- |
| 0.5mg q12h (Prograf level > 5 ng/ml) | 0.5 mg daily | 0.5mg every other day | Discontinue |
| 1mg daily (Prograf level < 5 ng/ml) | 0.5 mg daily | Discontinue | -- |
| 1mg daily (Prograf level > 5 ng/ml) | 0.5 mg daily | 0.5mg every other day | Discontinue |
| 1mg q12h (Prograf level < 5 ng/ml) | 1 mg daily | Discontinue | -- |
| 1mg q12h (Prograf level > 5 ng/ml) | 0.5 mg q12h | 0.5 mg daily | Discontinue |
| 2mg q12h (Prograf level < 5 ng/ml) | 1 mg q12 | 1 mg daily | Discontinue |
| 2mg q12h (Prograf level > 5 ng/ml) | 1.5 mg q12h | 1 mg q12h | Discontinue |
| 3 mg q12h | 2 mg q12h | 1 mg q12h | Discontinue |
| 4 mg q12h | 3 mg q12h | 2 mg q12h | Discontinue |
| 5 mg q12h | 3 mg q12h | 2 mg q12h | Discontinue |
| 6 mg q12h | 4 mg q12h | 2 mg q12h | Discontinue |
| 7 mg q12h | 5 mg q12h | 3 mg q12h | Discontinue |
| 8 mg q12h | 6 mg q12h | 3 mg q12h | Discontinue |
| 9 mg q12h | 6 mg q12h | 3 mg q12h | Discontinue |
| 10 mg q12h | 7 mg q12h | 4 mg q12h | Discontinue |

**RELATED DOCUMENT(S)/LINK(S):**

**Include Bela Workflow attachment**

**DEFINITIONS:** *(If applicable)*

N/A

**REFERENCES AND SOURCES OF EVIDENCE:**

Rostaing L et al. Switching from Calcineurin Inhibitor-based Regimens to a Belatacept-based Regimen in Renal Transplant Recipients: A Randomized Phase II Trial. *Clin J Am Soc Nephol* 2011; 6*:* 430-439.

Shen, J et al. Pharmacokinetics, Pharmacodynamics, and Immunogenicity of Belatacept in Adult Kidney Transplant Recipients. *Clin Drug Investig* 2014; 34: 117-126.

Adams A et al. Belatacept Combined with Transient Calcineurin Inhibitor Therapy Prevent Rejection and Promotes Improved Long-term Renal Allograf Function. *Am J Transplant* 2017; 17: 2922-2936.

**KEY WORDS:** Belatacept, tacrolimus, conversion

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| **REVIEW/APPROVAL SUMMARY:** Please select all Approving Bodies: |
| [ ] EUH MEC [ ]  EUHM MEC [ ] ESJH MEC [ ] EJCH MEC [ ] CNE Council [ ] System Operations |
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