



Cord Blood Bank Industry *Distribution Analysis*

FY18 – FY22

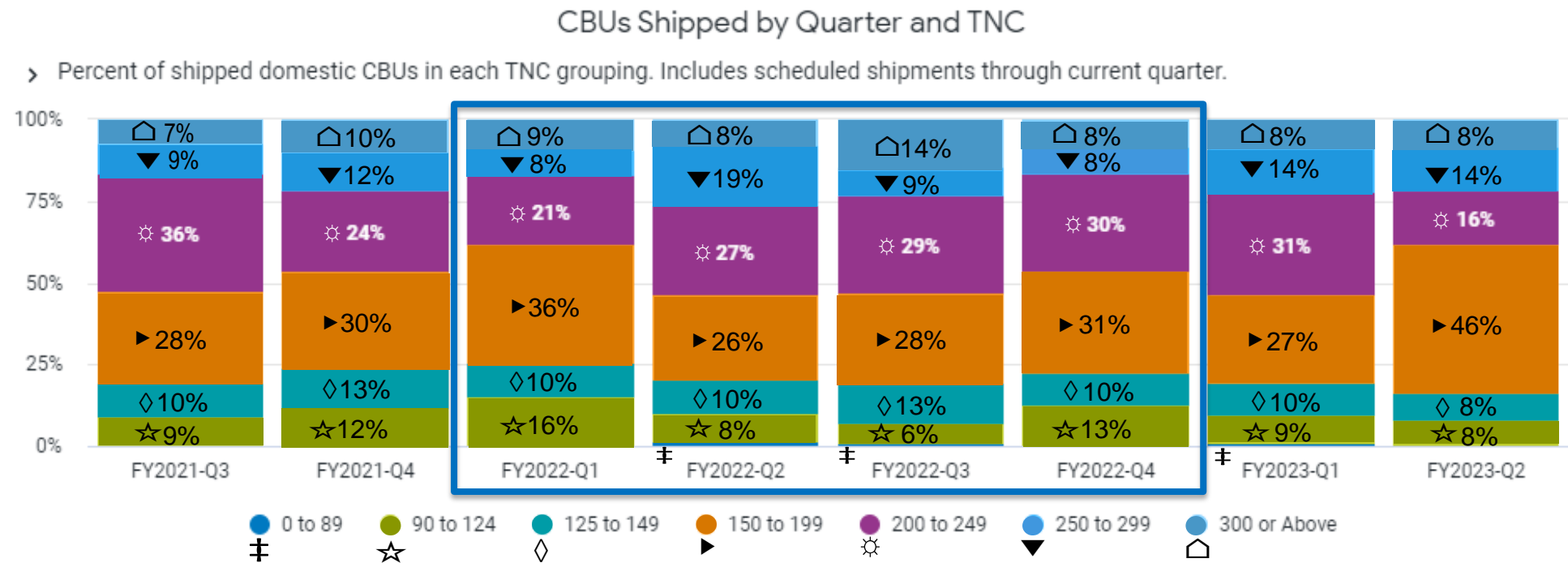
September 2023

CBU Distribution Analysis Parameters

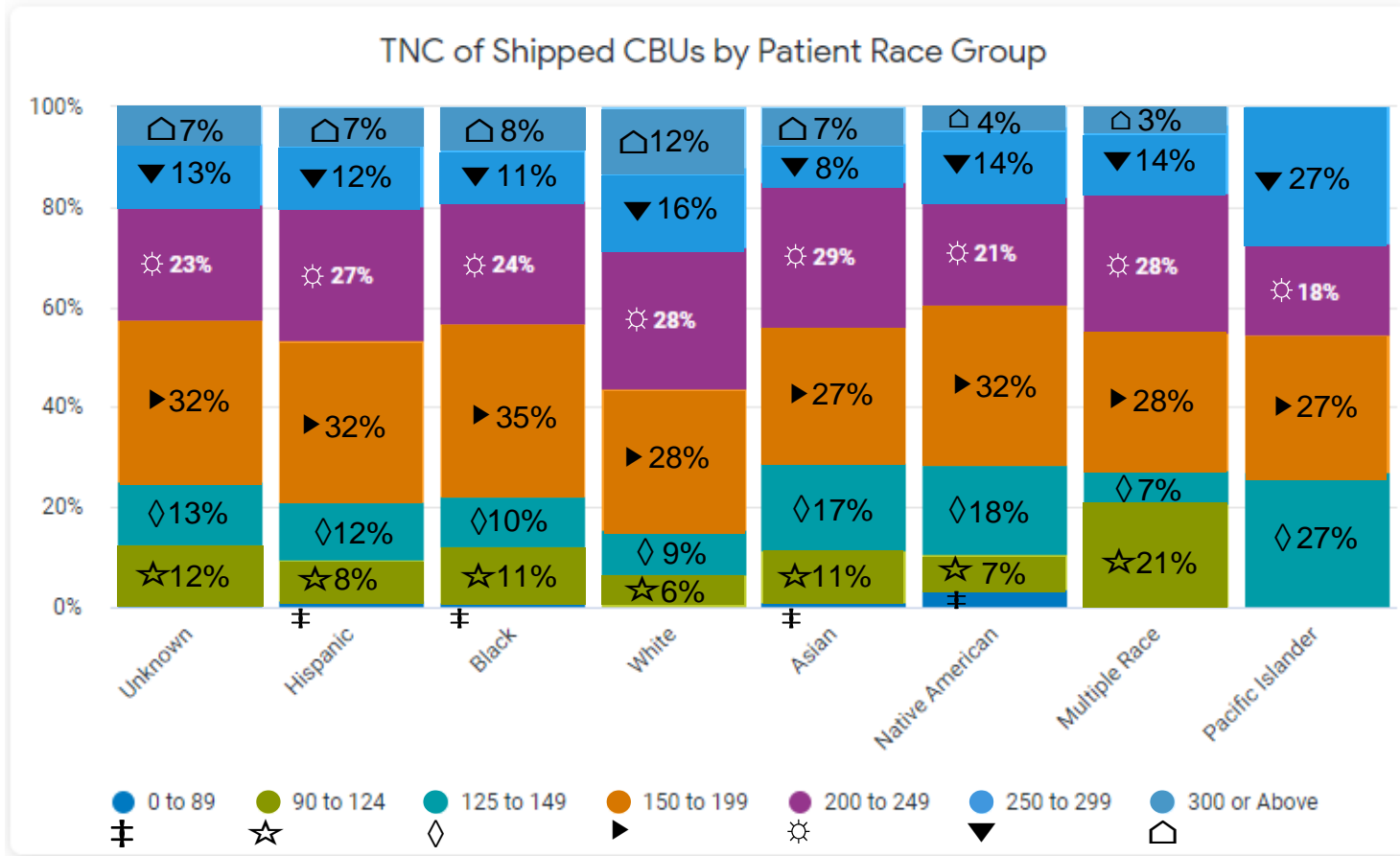
- Original Goal of Analysis
 - SPA-CC to perform a data analysis to determine inventory needs to meet patients' needs for HSCT.
 - SPA-CC provide recommendations on CBU registrations in terms of race and ethnicity as well as unit characteristics and specifications.
- Cord Blood Unit Demand includes shipment activity taking place from FY18 – FY22
 - Analysis may highlight the full 5 fiscal years or a sub-set of that timeframe
 - Distribution overview by TNC, CD34+, Patient Broad Race Group, & CBU Broad Race Group

CBUs Shipped by Quarter and TNC

- The majority (57%) of CBUs shipped in the past fiscal year (FY22) had TNC counts between 150 and 249.
- 79% of the CBUs shipped in the past fiscal year (FY22) had TNC counts $> 150 \times 10^7$, and 21% $< 150 \times 10^7$.



TNC of Shipped CBUs by Patient Race Group (FY18 – FY22)



- Higher TNC values are preferred regardless of race or ethnicity of donor or recipient.
- Lower TNC units have been utilized for patients of several racial / ethnic groups during the past five years.
- Note the predominance of units with TNC between $150-249 \times 10^7$ for all race groups but PI.

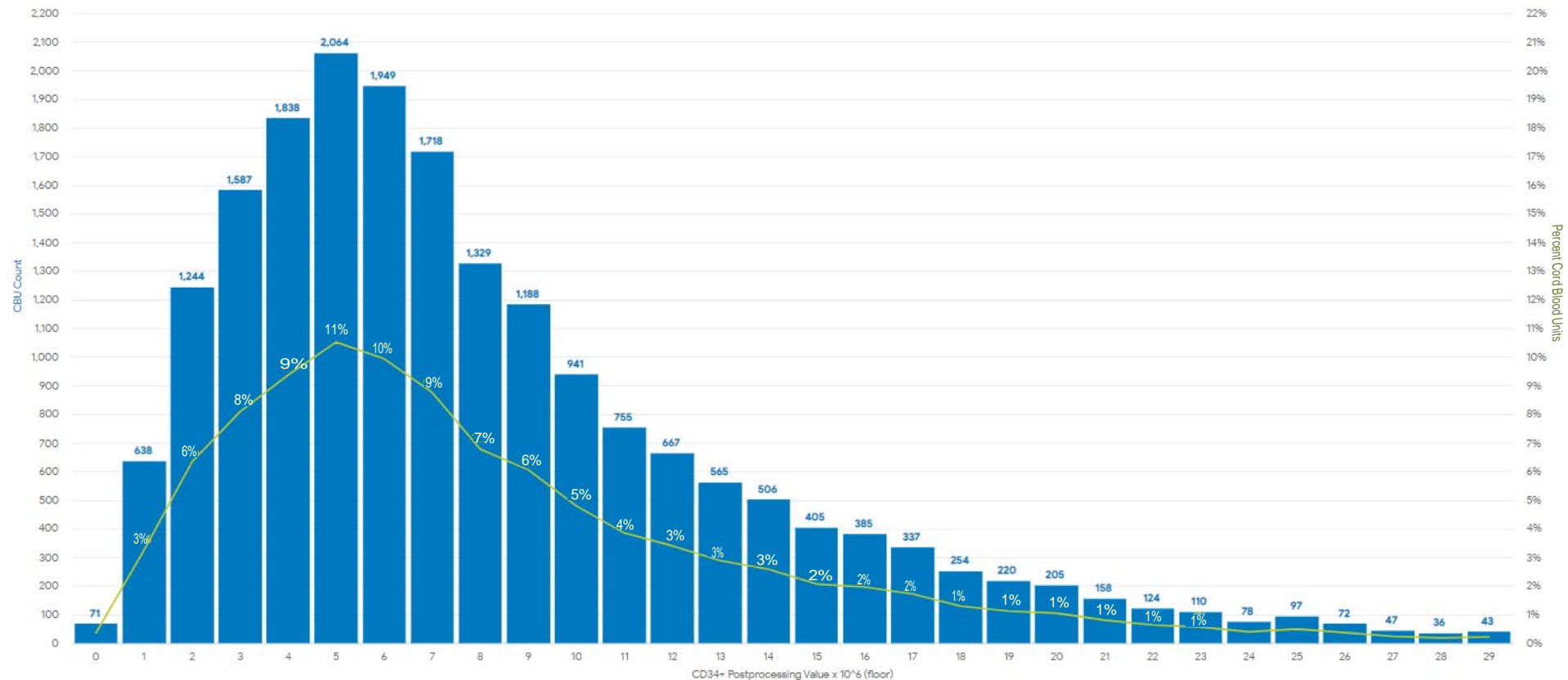
Recommended CBU TNC Count

- From a business perspective, NMDP would recommend the banking of CBUs with TNC counts greater than 150×10^7 , particularly for White, non-Hispanic donors.
- For non-White donors, NMDP would recommend a TNC greater than 125×10^7 . This lower threshold is based on findings such as: Non-Caucasian ethnicity is associated with reductions in hematopoietic measures of collected cord blood units.¹ Higher CD34+ and CFU content are factors associated with Caucasian race.² To suggest the same cell content for White and non-White units would be contrary to diversifying the national cord blood inventory.
- Pre-selecting donors for TNC is not realistic, as collection volume is dependent on biological factors and collection technique.

1. Akyurekli C, Chan JY, Elmoazzen H, Tay J, Allan DS. Impact of ethnicity on human umbilical cord blood banking: a systematic review. *Transfusion*. 2014 Aug;54(8):2122-7. doi: 10.1111/trf.12630. Epub 2014 Apr 4. PMID: 24697816.
2. Page KM, Mendizabal A, Betz-Stablein B, Wease S, Shoulars K, Gentry T, Prasad VK, Sun J, Carter S, Balber AE, Kurtzberg J. Optimizing donor selection for public cord blood banking: influence of maternal, infant, and collection characteristics on cord blood unit quality. *Transfusion*. 2014 Feb;54(2):340-52. doi: 10.1111/trf.12257. Epub 2013 May 27. PMID: 23711284; PMCID: PMC3766489.
3. Karen K Ballen, Joanne Kurtzberg, Thomas A Lane, Bruce R Lindgren, John P Miller, Denis Nagan, Bruce Newman, Neil Rupp, N.Rebecca Haley, Racial diversity with high nucleated cell counts and CD34 counts achieved in a national network of cord blood banks, *Biology of Blood and Marrow Transplantation*, Volume 10, Issue 4, 2004, Pages 269-275
4. https://www.rand.org/content/dam/rand/pubs/research_reports/RR1800/RR1898/RAND_RR1898.pdf

CBUs Shipped by CD34 x 10⁶ Grouping (All Shipments Facilitated)

- Demonstrates the preference for larger CBUs, with >90% of units shipped containing $\geq 3 \times 10^6$ CD34+ cells.
- Given these factors, NMDP recommends a minimum threshold for CD34+ cell content to be $\geq 3 \times 10^6$.



Recommended CBU CD34+ Count

- Are there lower limits we should consider when setting minimum standards for the NCBI? (e.g., CD34+ count is $\geq 1.25 \times 10^6$...)
 - Enumeration of CD34+ cells is not fully standardized and can vary by lab depending on gating strategies.
 - [FDA's Biologic License Application Guidance](#) requires $\geq 1.25 \times 10^6$ viable CD34+ cells/unit and is based on CD34+ cells $\geq 0.25\%$ of TNC prior to freezing.
 - Applying that percentage to NMDP's recommended TNC of 150×10^7 for CBUs from White donors and 125×10^7 for ethnically diverse donors suggests a minimum CD34+ cell count of 3.75×10^6 and 3.125×10^6 respectively.
 - These post-processing/pre-freeze counts yield the Cord Blood Transplant Guidelines recommended minimum cell dose of $1.5 \times 10^5/\text{kg}$ CD34+ ^{1,2,3} for patients weighing 25 kg and 20 kg respectively.

1. Jason Dehn, Stephen Spellman, Carolyn K. Hurley, Bronwen E. Shaw, Juliet N. Barker, Linda J. Burns, Dennis L. Confer, Mary Eapen, Marcelo Fernandez-Vina, Robert Hartzman, Martin Maiers, Susana R. Marino, Carlheinz Mueller, Miguel-Angel Perales, Raja Rajalingam, Joseph Pidala; Selection of unrelated donors and cord blood units for hematopoietic cell transplantation: guidelines from the NMDP/CIBMTR. *Blood* 2019; 134 (12): 924–934.
2. Politikos I, Davis E, Nhaissi M, Wagner JE, Brunstein CG, Cohen S, Shpall EJ, Milano F, Scaradavou A, Barker JN; American Society for Transplantation and Cellular Therapy Cord Blood Special Interest Group. Guidelines for Cord Blood Unit Selection. *Biol Blood Marrow Transplant.* 2020 Dec;26(12):2190-2196. doi: 10.1016/j.bbmt.2020.07.030. Epub 2020 Jul 28. PMID: 32736011.
3. <https://network.bethematchclinical.org/education/education-catalog/donor-and-cord-blood-unit-selection-guidelines/>

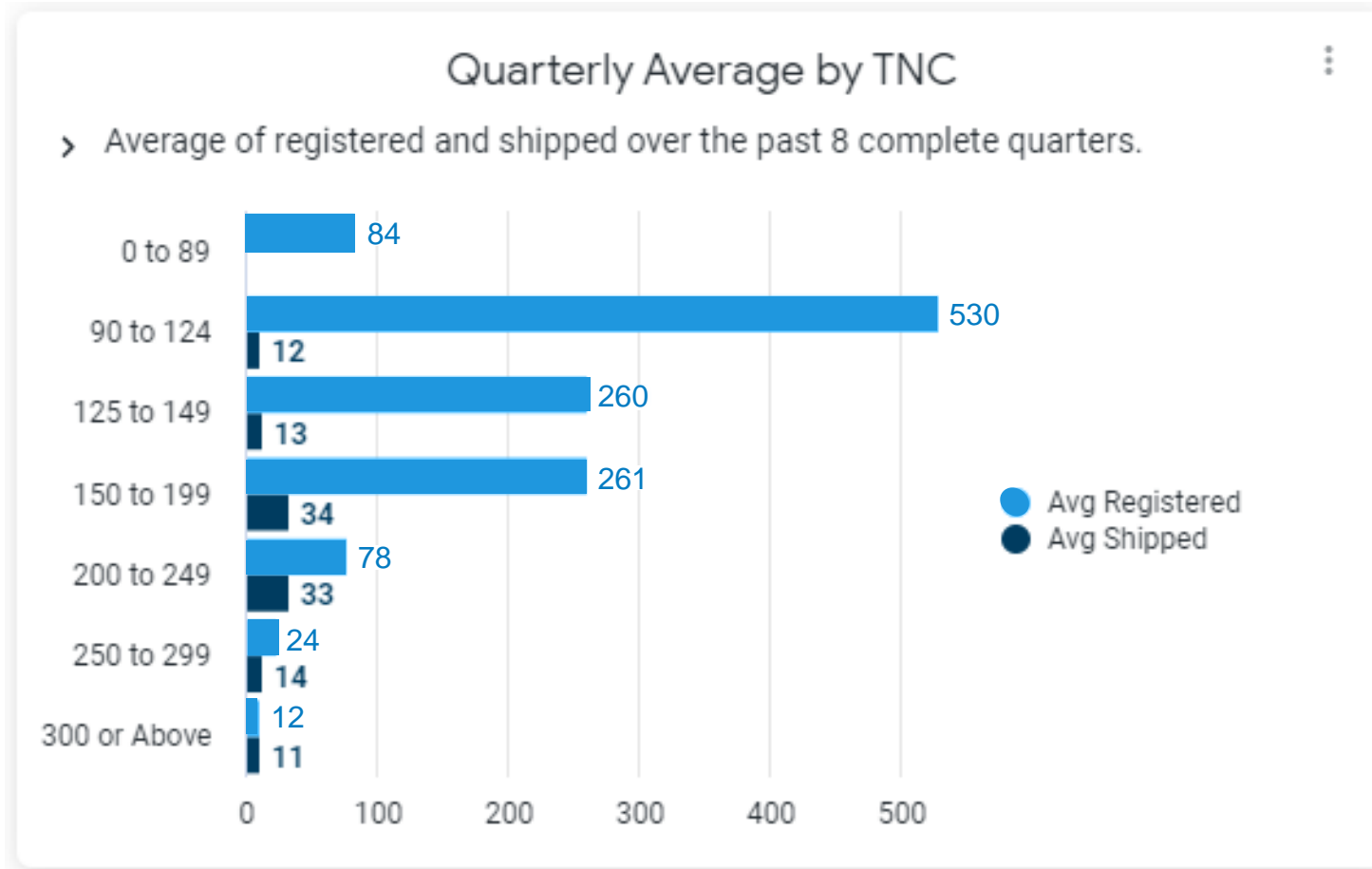
Mean & median TNC shipped (FY18 – FY22)

CBUs	Mean	Median
All (NCBI & non-NCBI)	205 x 10 ⁷	197 x 10 ⁷
NCBI only	207 x 10 ⁷	199 x 10 ⁷

Mean & Median TNC of largest 80% of CBUs shipped (FY18 – FY22)

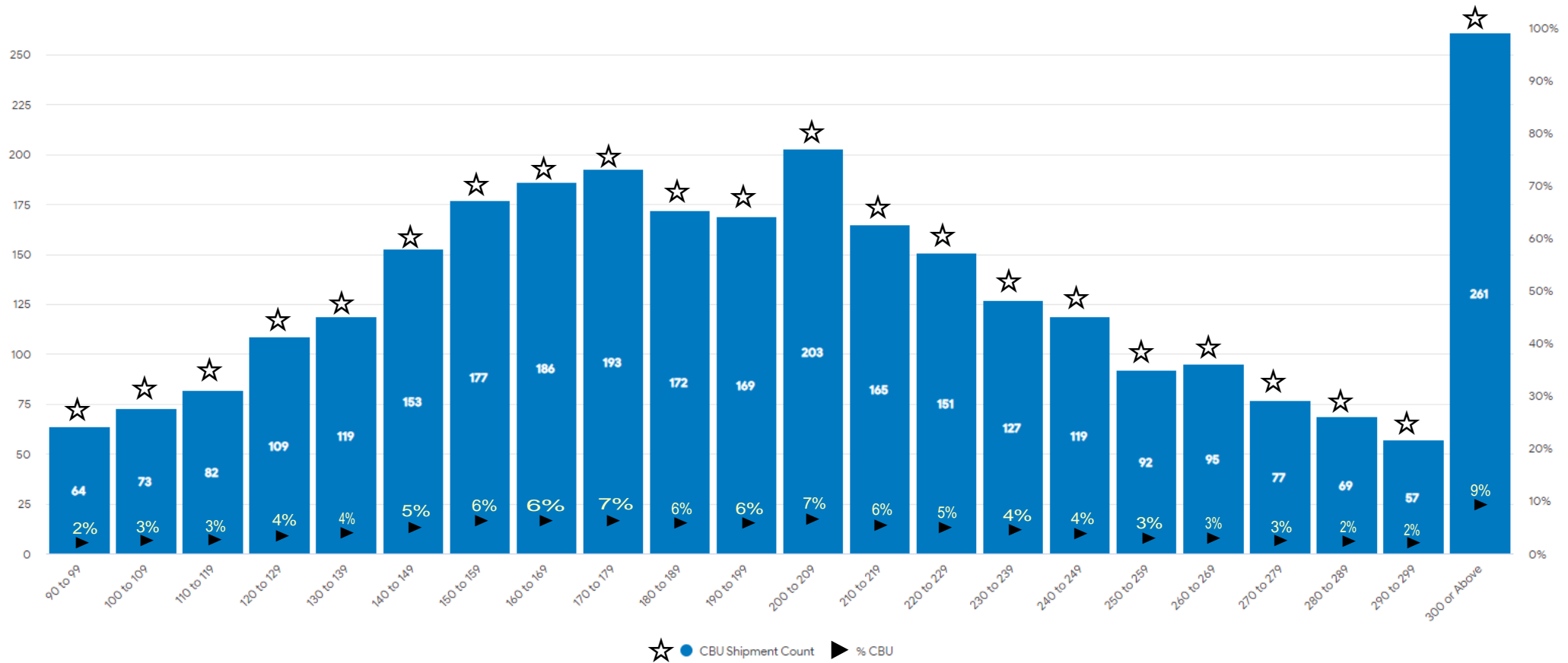
CBUs	Mean	Median
All (NCBI & non-NCBI)	226 x 10 ⁷	212 x 10 ⁷
NCBI only	228 x 10 ⁷	215 x 10 ⁷

Would the NCBI banks be able to meet the demand if the TNC requirement were increased above 90×10^7 to a higher requirement?

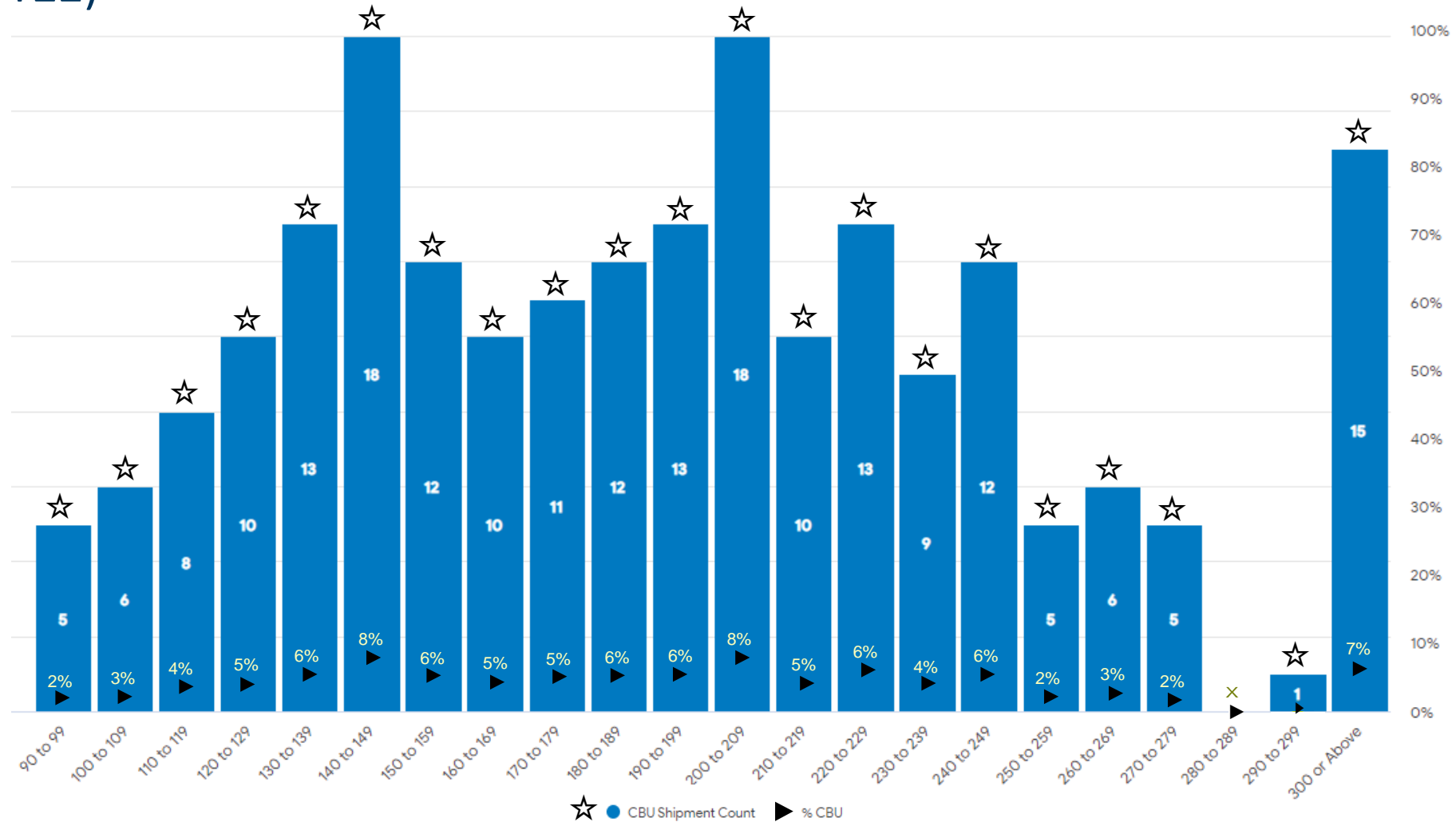


- Yes, banks register many more units in the smaller categories than are shipped, particularly those $< 125 \times 10^7$.
- Many banks already have policies in place that require higher TNC criteria for banking White units than ethnically diverse units.

Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)

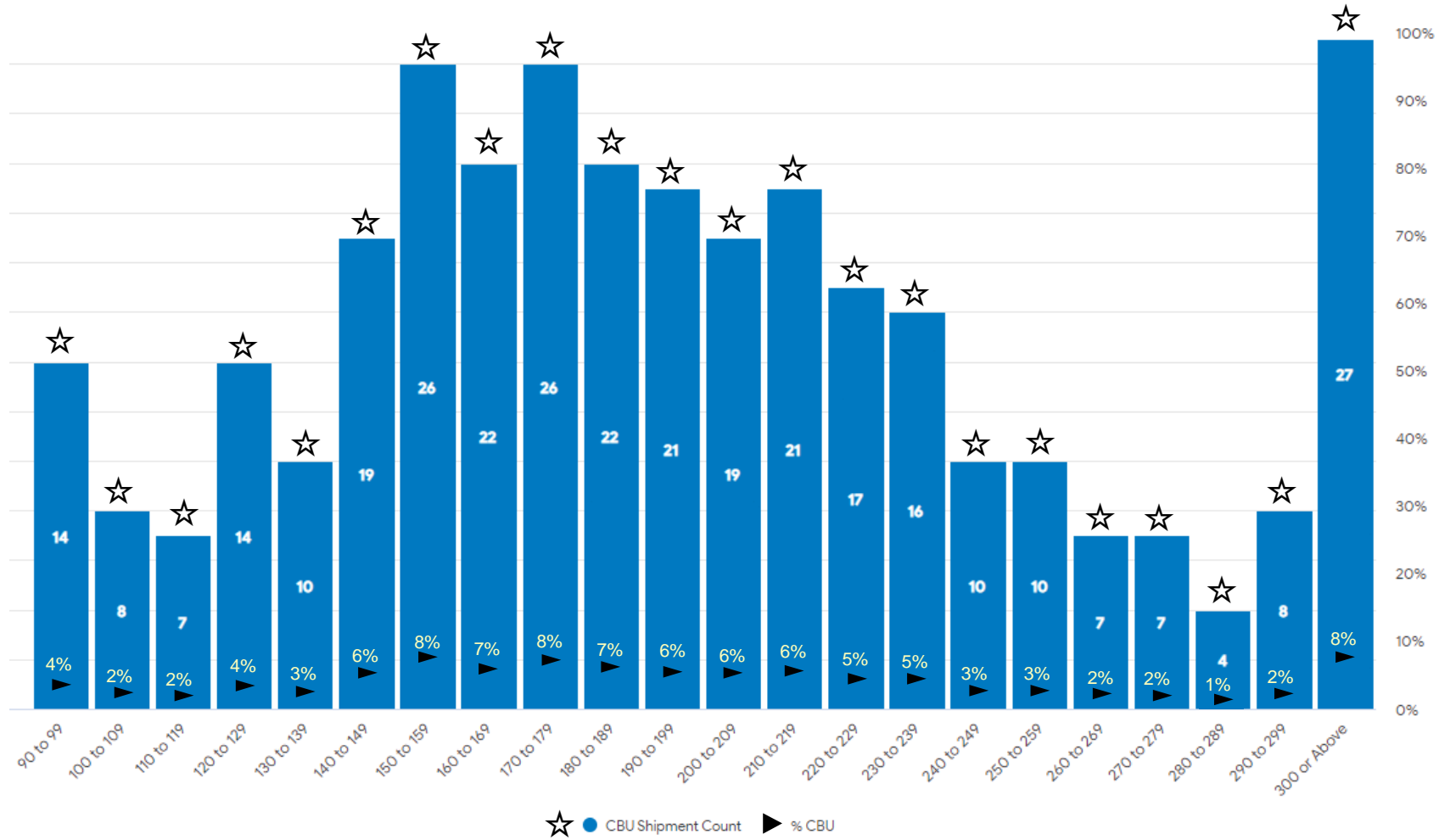


Asian Patient Race Group – Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)

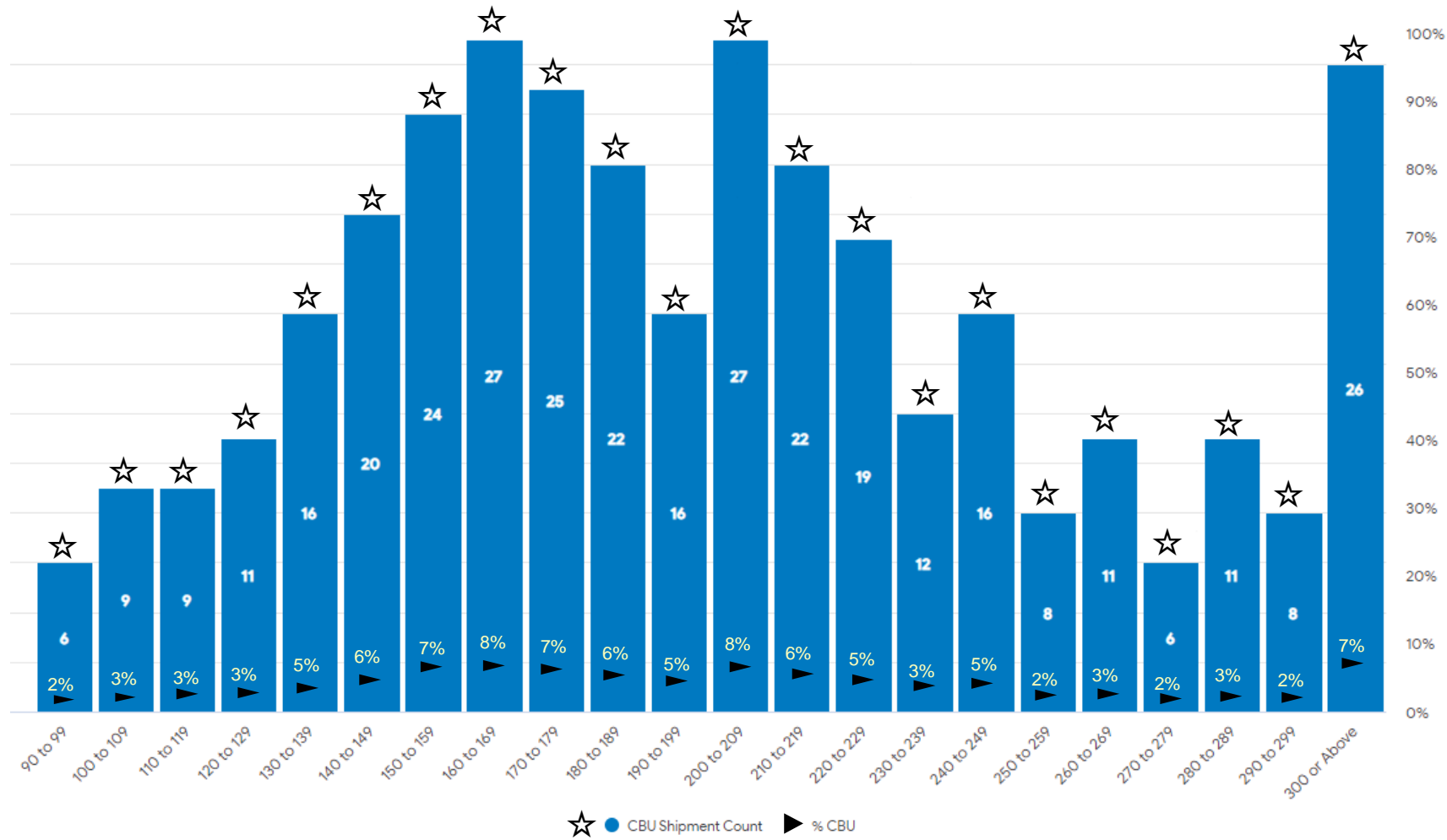


Black Patient Race Group –

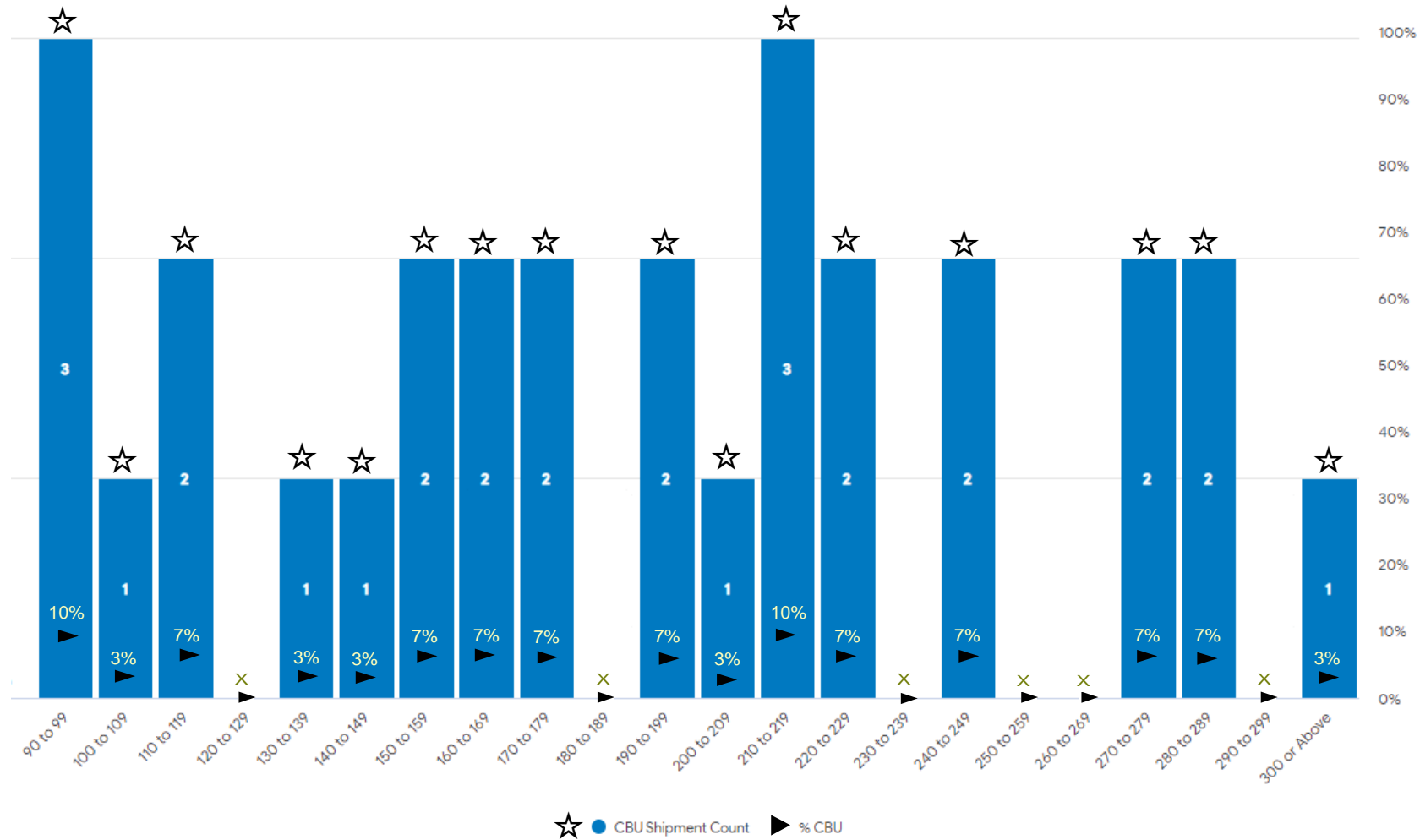
Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)



Hispanic Patient Race Group – Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)

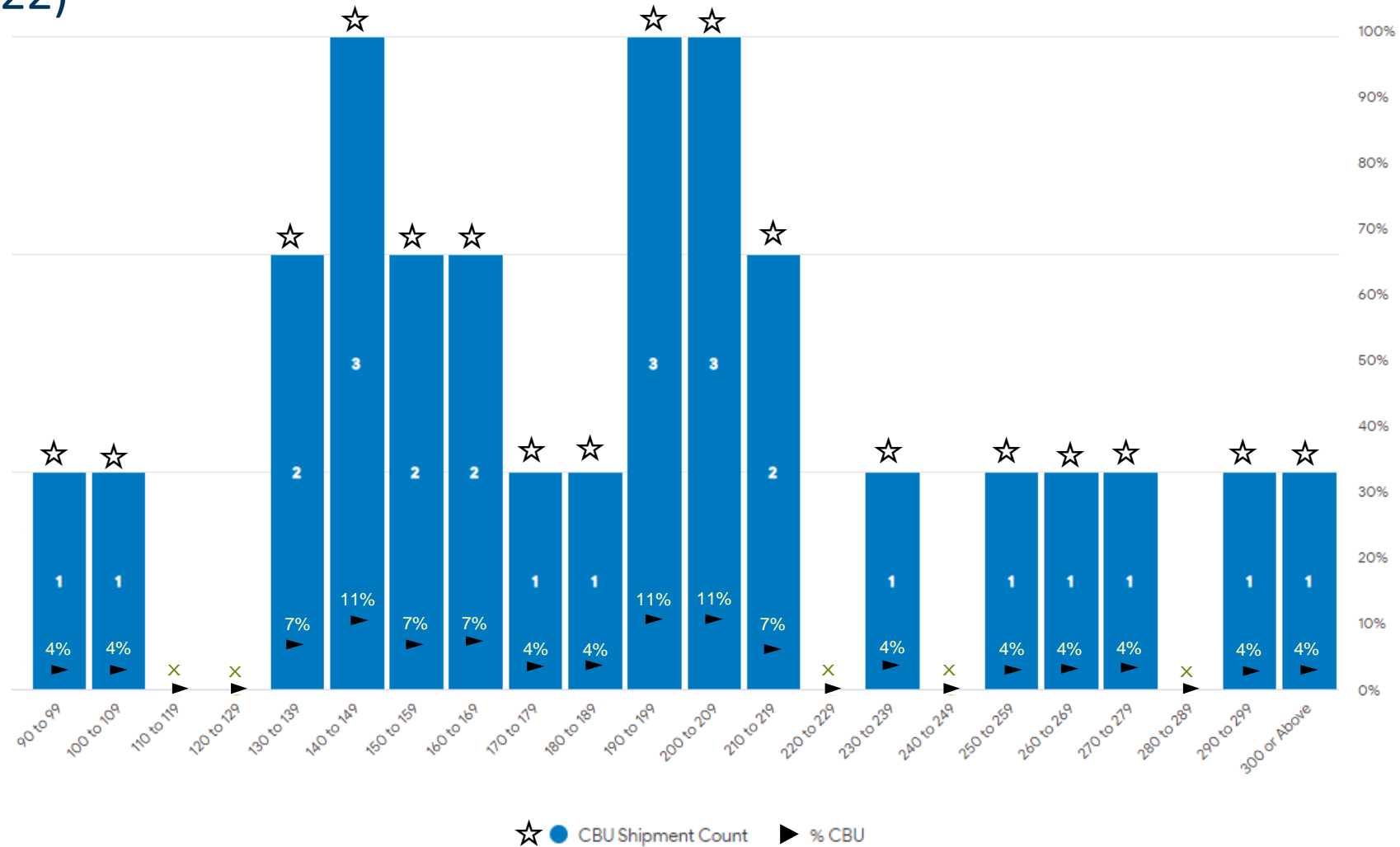


Multi-Race Patient Race Group – Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)



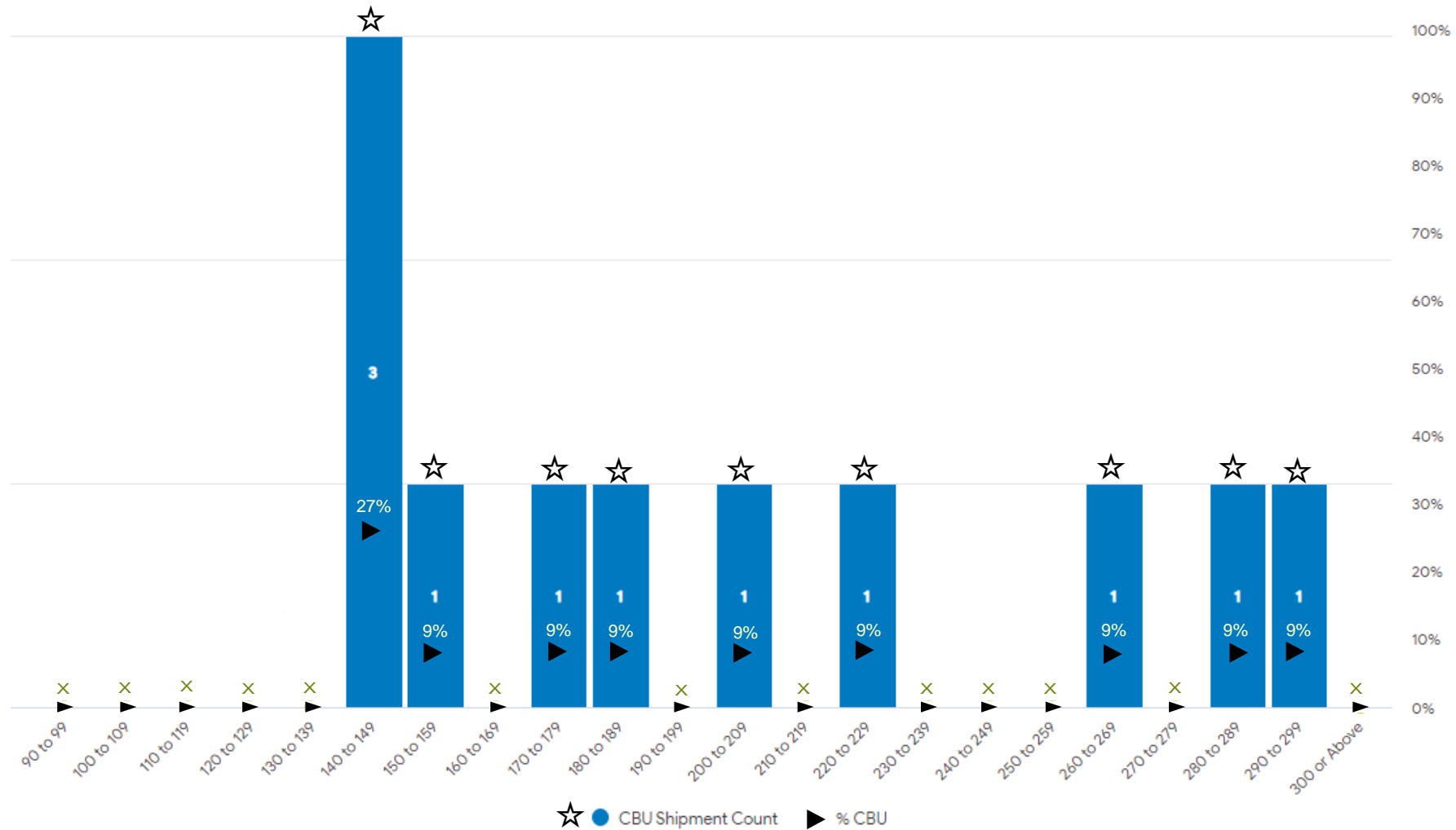
Native American Race Group –

Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)

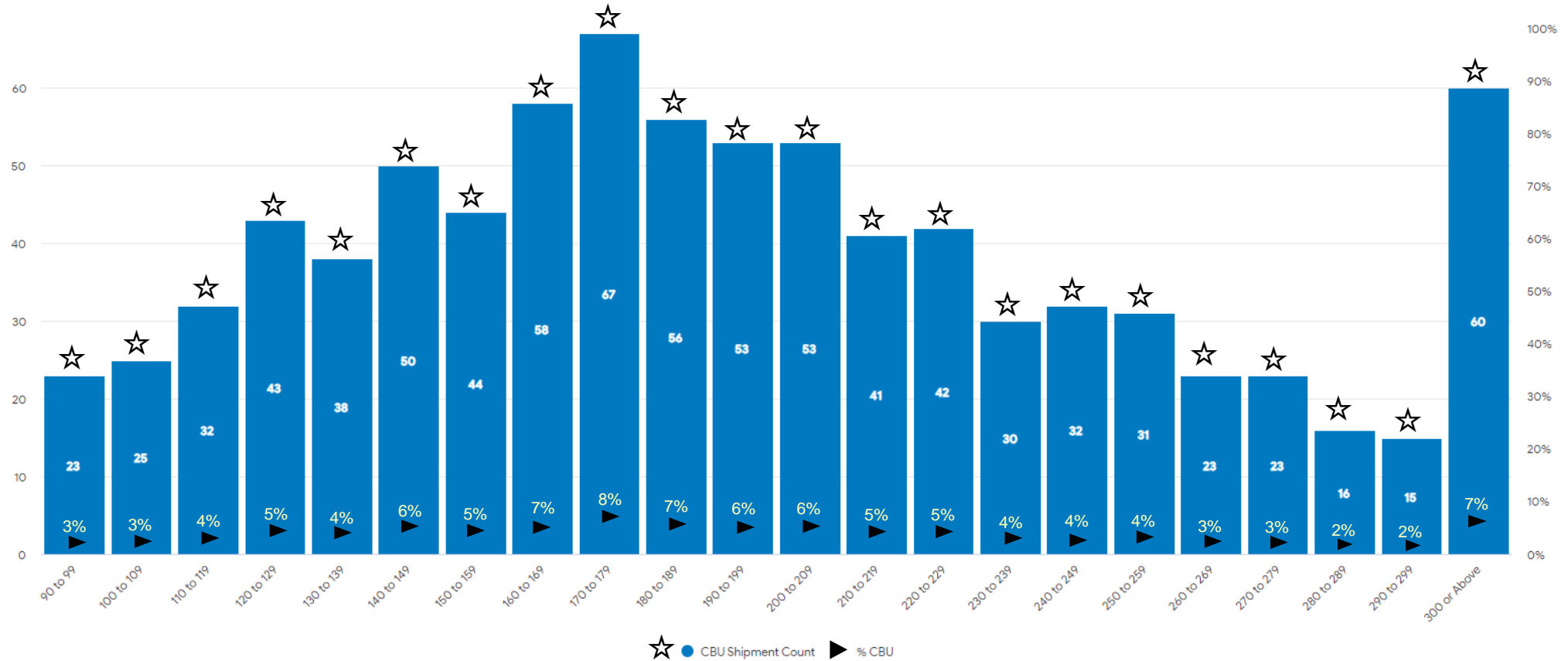


Pacific Islander Patient Race Group –

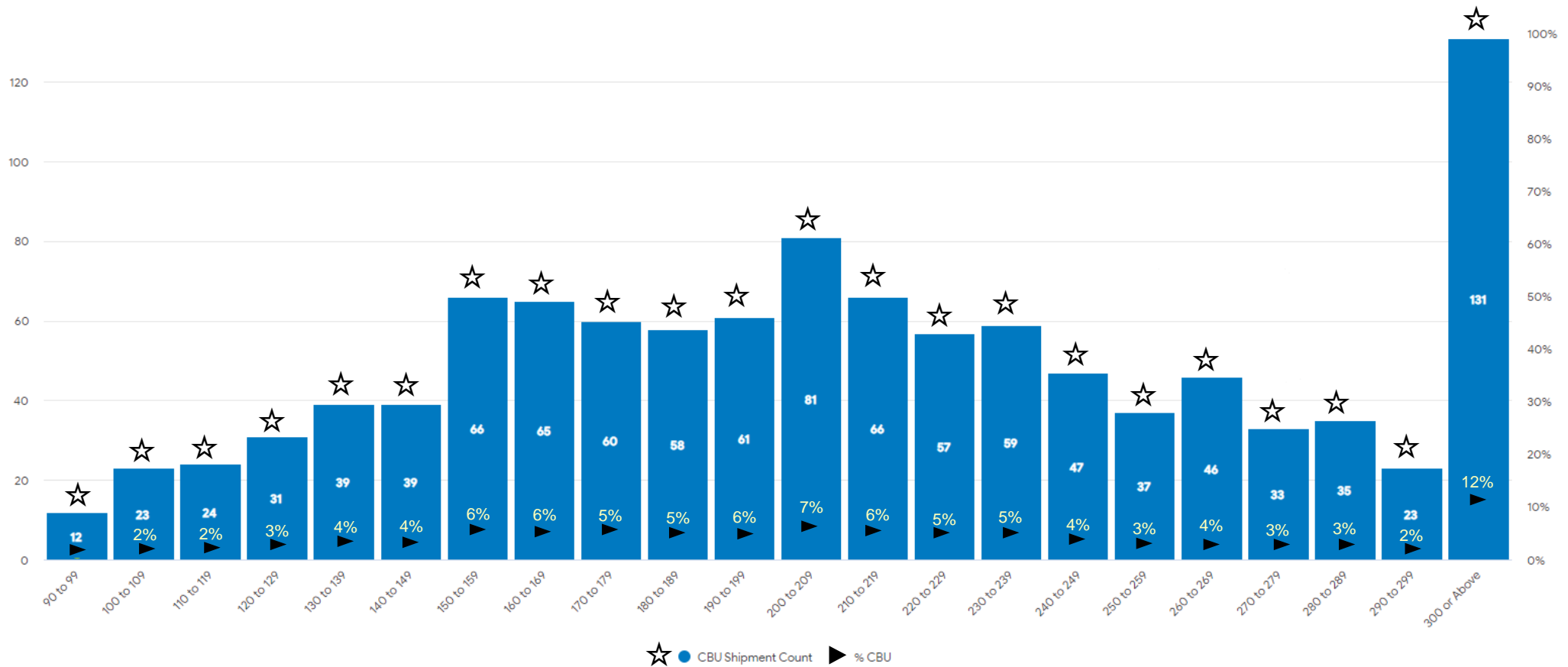
Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)



Unknown Patient Race Group – Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)



White Patient Race Group – Count and Percentage of Shipments by TNC Group last 5 years cumulative (FY18 – FY22)

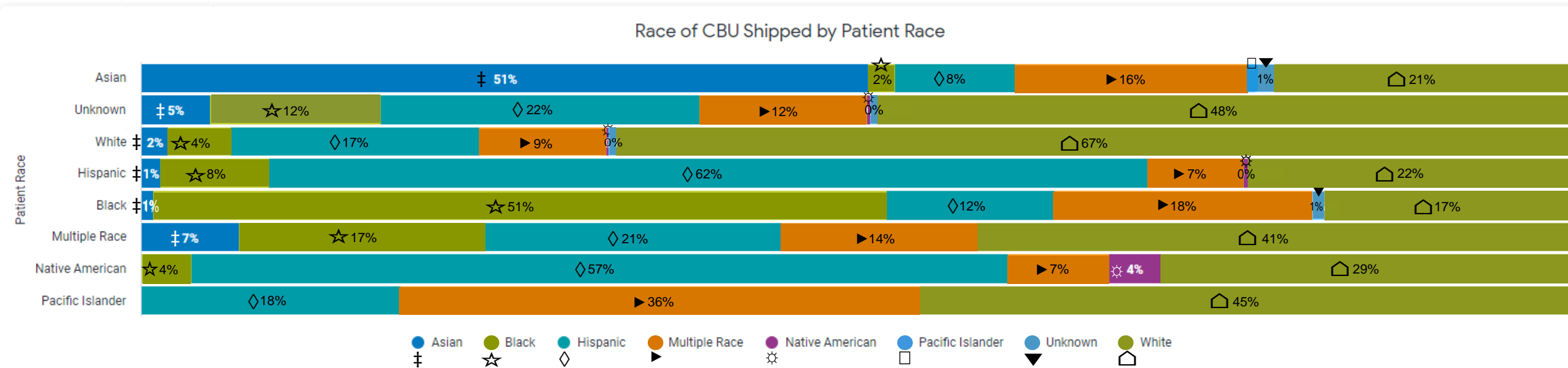


Can Caucasian (non-Hispanic) units be increased to meet the transplant need for other race and ethnicities since they are more easily collected?

- White units are frequently utilized for patients from other race/ethnicities.
- Between FY 2018 – FY 2022, the use of White units ranged from 17% for African American/Black patients to 67% for White patients.
- Patients of all races/ethnicities benefit from having units available from donors other than their own race/ethnicity.
- Discouraging the collection of White units would negatively impact the ability to use these CBUs in treating all patients regardless of race/ethnicity.

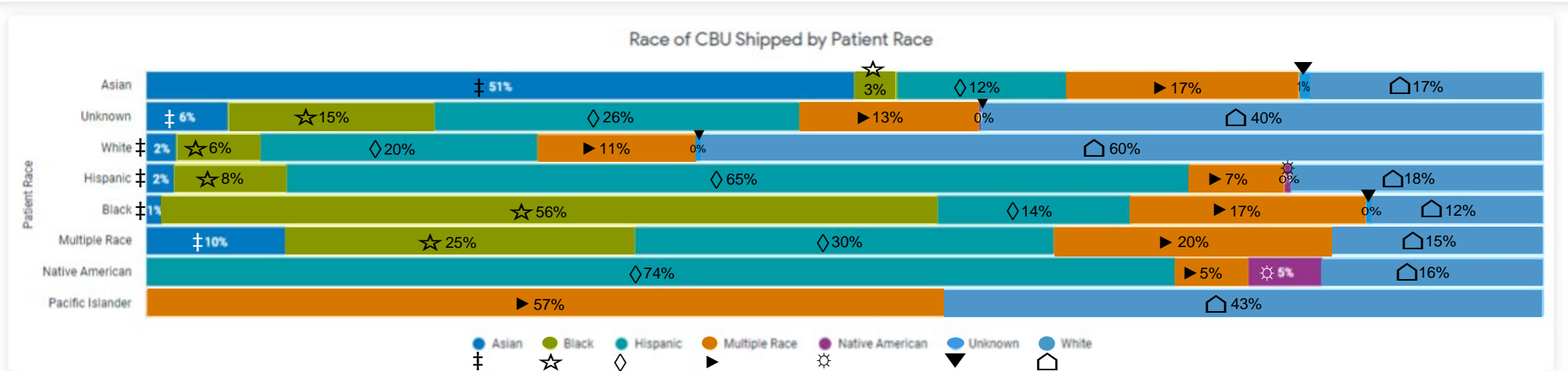
Which units are likely to be released for transplant by race/ethnicity?

- Patients receive a CBU that is the same race/ethnicity as their own ~50% of the time.
- 50% of the time, patients are receiving units which are not of their same R/E.
- White and Hispanic patients source grafts from their own race ~65% of the time.
- Not surprisingly, Multi-Race patients source units from a variety of races.



All NCBI – FY18 – FY22 – By Recipient Race

NCBI Flag Patient HRSA Race Group – Short Name CBU Shipment Fiscal Year

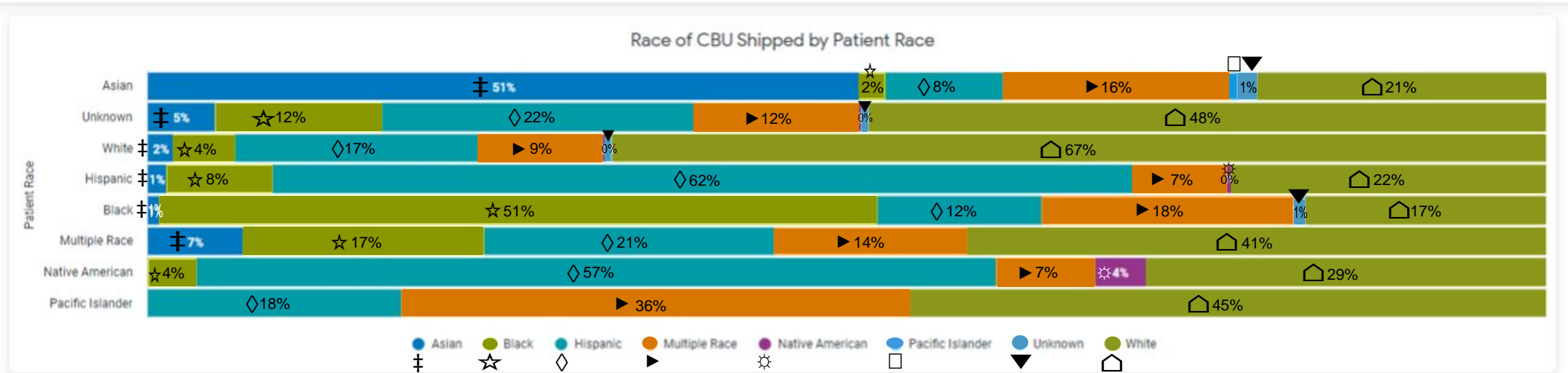


Race of CBU Shipped by Patient Race (table)

Patient Race	Asian		Black		Hispanic		Multiple Race		Native American		Unknown		White		Total CBU Shipment Count
	CBU Shipment Count	% of Total Patient Race	CBU Shipment Count	% of Total Patient Race	CBU Shipment Count	% of Total Patient Race	CBU Shipment Count	% of Total Patient Race	CBU Shipment Count	% of Total Patient Race	CBU Shipment Count	% of Total Patient Race	CBU Shipment Count	% of Total Patient Race	
Asian	67	51%	4	3%	16	12%	22	17%	x	x	1	1%	22	17%	132
Unknown	33	6%	83	15%	147	26%	72	13%	1	0%	1	0%	225	40%	562
White	15	2%	42	6%	138	20%	79	11%	x	x	2	0%	419	60%	695
Hispanic	5	2%	20	8%	161	65%	17	7%	1	0%	x	x	45	18%	249
Black	3	1%	141	56%	35	14%	43	17%	x	x	1	0%	31	12%	254
Multiple Race	2	10%	5	25%	6	30%	4	20%	x	x	x	x	3	15%	20
Native American	x	x	x	x	14	74%	1	5%	1	5%	x	x	3	16%	19
Pacific Islander	x	x	x	x	x	x	4	57%	x	x	x	x	3	43%	7

All CBUs (NCBI & Non-NCBI) – FY18 – FY22 – By Recipient Race

NCBI Flag Patient HRSA Race Group – Short Name CBU Shipment Fiscal Year



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Asian	109	51%	4	2%	18	8%	35	16%			1	0%	3	1%	44	21%	214
Unknown	42	5%	103	12%	192	22%	101	12%	2	0%			4	0%	417	48%	861
White	21	2%	48	4%	191	17%	98	9%	1	0%	1	0%	5	0%	732	67%	1,097
Hispanic	5	1%	27	8%	219	62%	24	7%	1	0%					80	22%	356
Black	3	1%	174	51%	40	12%	61	18%					3	1%	58	17%	339
Multiple Race	2	7%	5	17%	6	21%	4	14%							12	41%	29
Native American			1	4%	16	57%	2	7%	1	4%					8	29%	28
Pacific Islander					2	18%	4	36%							5	45%	11

Conversation...

