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NCCN Guidelines Panel: Prevention and Treatment of Cancer Related Infections

On behalf of Blue Spark Technologies, I respectfully request the NCCN Prevention and Treatment of Cancer Related Infections panel to review the enclosed data for inclusion of the Temp Traq continuous temperature monitor as a means of reducing time to treatment for high risk patients, both inpatient or for those being treated at home.

Specific changes recommended: Include the use of Temp Traq to Outpatient Management of Low Risk patients being treated for infection to allow for remote monitoring and early identification of increasing temperature. Include the use of Temp Traq for High Risk patients being treated in the hospital for early identification of increasing temperature.

FDA Clearance: The Wireless thermometer, model TT-100, is a battery-operated electronic device with intended use of measuring human body temperature precisely. This device is single-use and intended for armpit temperature measurement for persons of all age.

Rationale: In support of the proposed change to NCCN Prevention and Treatment of Cancer Related Infections data from completed studies shows early identification of fever or worsening of fever which can potentially reduce the need for hospitalizations, reduce cost of care and improve overall quality.

The following articles are submitted in support of this proposed change.

- Dambrosio, N., Gannon, J., Eager, J., Sylvan, D., Lima, M. J., Levitan, N., & Malek, E. (2017). Feasibility of monitoring of body temperature for patients undergoing stem cell transplant or intensive chemotherapy. *Journal of Clinical Oncology, 35*(15_suppl). doi:10.1200/jco.2017.35.15_suppl.e21630
- Dambrosio, N., Porter, M., Bauer, E., Levitan, N., Liedtke, D., de Lima, M., & Malek, E. (2018). Identifying Neutropenic Fever Earlier: An Application of a Skin Patch for Continuous Temperature Monitoring. *Blood,* 132(Suppl 1), 4718. Accessed June 25, 2019. https://doi.org/10.1182/blood-2018-99-114181.
- Sampson, M, Hickey, V, Huber, J, Alonso, PB, Davies, SM, Dandoy, CE. Feasibility of continuous temperature monitoring in pediatric immunocompromised patients: A pilot study. *Pediatr Blood Cancer*. 2019; 66:e27723. https://doi.org/10.1002/pbc.27723
- National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections. Vol 1.2019. https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf
- Krzyzanowska, M., Walker-Dilks, C., Atzema, C., Morris, A., Gupta, R., Halligan, R., . . . Mccann, K. (2016). Approach to fever assessment in ambulatory cancer patients receiving chemotherapy: A clinical practice guideline. *Current Oncology, 23*(4), 280. doi:10.3747/co.23.3098
- Kapil, P., Macmillan, M., Carvalho, M., Lymburner, P., Fung, R., Almeida, B., . . . Enright, K. (2016). Assessment of Fever Advisory Cards (FACs) as an Initiative to Improve Febrile

Neutropenia Management in a Regional Cancer Center Emergency Department. *Journal of Oncology Practice, 12*(9). doi:10.1200/jop.2015.009183

Sincerely,

John Gannon